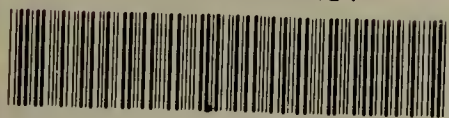


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INTERIM FINAL POLICY

BWSC/ORS-95-141



# GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

In Support of the Massachusetts Contingency Plan



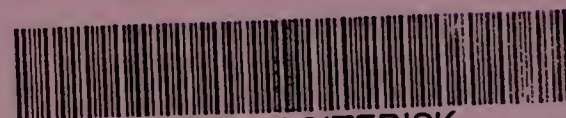
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MASSACHUSETTS  
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Massachusetts Department of Environmental Protection  
Bureau of Waste Site Cleanup  
and  
Office of Research and Standards

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July, 1995



DISPOSALSITERISK

*Published by:* William Francis Galvin, Secretary of the Commonwealth





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Executive Office of Environmental Affairs

## Department of Environmental Protection

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Governor

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### GUIDANCE FOR DISPOSAL SITE RISK CHARACTERIZATION

In Support of the Massachusetts Contingency Plan

Interim Final Policy #WSC/ORS-95-141

This Interim Final Policy provides guidance for conducting and documenting risk characterizations and related investigatory activities for disposal sites contaminated by oil and/or hazardous material. This information is intended solely for guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. The regulations related to the characterization of risk of harm to health, safety, public welfare and the environment contain both specific and general requirements. In addition to summarizing specific requirements, this document also provides guidance on what approaches the Department considers acceptable for meeting the general requirements set forth in the regulations. Parties using this guidance should be aware that there may be other acceptable alternatives to this guidance for achieving compliance with such general regulatory requirements.

The regulatory citations provided throughout this document are not meant to be, and should not be relied upon to be, a complete list of all the regulatory requirements for risk characterization. Parties undertaking a risk characterization for a site should consult 310 CMR 40.0000 (MCP) for applicable requirements.

This policy supersedes the 1989 version of the *Guidance for Disposal Site Risk Characterization* (Policy #WSC/ORS-141-89) and the 1991 *Suggested Outline, Content and Format of Phase II Human Health Risk Assessment Scope of Work* (Policy #WSC-140-91).

James C. Colman  
Assistant Commissioner  
Bureau of Waste Site Cleanup

Date

Carol Rowan West  
Director  
Office of Research and Standards

Date



## FOREWORD

This document provides guidance for conducting risk characterizations pursuant to Subpart I of the Massachusetts Contingency Plan (MCP). This is an update of the 1989 *Guidance for Disposal Site Risk Characterization*, reflecting the changes in the 1993 and 1995 revisions of the MCP.

The risk assessment procedures described herein are intended to be generally consistent with guidance provided by the U.S. Environmental Protection Agency, particularly the *Risk Assessment Guidance for Superfund* (US EPA, 1989) and related material. This guidance includes additional direction concerning the specific requirements of M.G.L. Chapter 21E, the Massachusetts Oil and Hazardous Materials Release Prevention and Response Act, and the MCP. Utilization of this guidance will lead to risk characterizations that are consistent from site to site and remedial decisions that are protective of health, safety, public welfare and the environment.

The increase in the volume of the guidance relative to the document published in 1989 reflects an effort to more fully describe DEP policies and practices. Since DEP no longer exercises direct oversight at all sites, it is necessary to provide more explicit guidance on risk assessment procedures that are acceptable for the purpose of meeting the MCP requirements. The increased volume of the risk assessment guidance does *not* represent an increase in risk assessment requirements. In fact, in many cases, the MCP now makes the risk assessment process much simpler, faster and less expensive than in the past.

This version of the guidance is an *Interim Final Policy*, meaning that it is being made available to MADEP staff and the general public with the expectation that day-to-day use of this material will provide insight into how the guidance may be improved. The Massachusetts Department of Environmental Protection (MADEP) Bureau of Waste Site Cleanup and Office of Research and Standards are soliciting comments on whether this material provides sufficient guidance to demonstrate that the requirements of the MCP have been met, and on specific technical approaches and requirements described herein. Users of this document are encouraged to submit comments on both its content and format. Any recommendations for making the document more workable would be welcomed. Please submit comments on this document by **December 31, 1995** to:

Nancy Bettinger  
Department of Environmental Protection  
Office of Research and Standards  
One Winter Street, 3rd Fl  
Boston, MA 02108

Technical questions about the material presented herein may be addressed to the Risk Analysis Group staff within the Office of Research and Standards:

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The Massachusetts DEP would like to thank the members of two workgroups of human health and ecological risk assessors who met to discuss and comment on drafts of this material and who generously contributed their time and expertise to this project. Participants in these workgroups include:

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## FOR MORE INFORMATION...

### MCP HOTLINE

The *MCP Hotline* is staffed by MADEP BWSC staff with detailed knowledge of the Bureau's regulations and policies. The *Hotline* is reached through the Department's *Infoline*, a toll-free information service providing answers to general DEP questions, permit application kits, DEP seminar information, Compliance Fee assistance, and referrals to technical experts.

from area code 617 and outside Massachusetts  
**617-338-2255**

from area codes 413 and 508  
**1-800-462-0444**

The *MCP Hotline* is the first choice, « 1 », on the *Infoline's* menu of options.

### MADEP COMPUTER BULLETIN BOARD SYSTEM

The MADEP Office of Research and Standards has established a computer bulletin board system for 24-hour access to many DEP policies and regulations, particularly related to M.G.L. c.21E and the Massachusetts Contingency Plan.

#### SETTINGS:

**MODEM #:** 617-292-5546

**SPEED:** up to 14,400 Baud

**DATA:** 8

**STOP:** 1

**PARITY:** None

Questions?

Call Systems Operator (SYSOP)  
Michelle Bornstein at 617-556-1052.

### STATE HOUSE BOOKSTORE

Copies of the Massachusetts state laws (e.g., M.G.L. Chapter 21E), regulations (e.g., the Massachusetts Contingency Plan), and other publications (e.g., *Background Documentation for the Development of the MCP Numerical Standards*) may be purchased from:

State Bookstore  
Room 116  
State House  
Boston, MA 02133  
(617) 727-2834

or

Western Office of the  
Massachusetts Secretary of State  
436 Dwight Street  
Springfield, MA 01103  
(413) 784-1376

### REGIONAL SERVICE CENTERS

MADEP operates 4 Regional Service Centers to bring information and assistance closer to those who need it. The Service Center in your area is the first place to call or visit for general information, access to DEP documents and files, and environmental education materials. The Centers are located in the four DEP Regional Offices:

Western Region: (413) 784-1100 x 214  
Springfield

Central Region: (508) 792-7683  
Worcester TDD: (508) 767-2788

Northeast Region: (617) 932-7677  
Woburn TDD: (617) 932-7679

Southeast Region: (508) 946-2714  
Lakeville TDD: (508) 946-2795

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## INTRODUCTION

This document provides guidance for conducting and documenting risk characterizations and related investigatory activities for disposal sites contaminated by oil and/or hazardous material. This information is intended solely for guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. The regulations related to the characterization of risk of harm to health, safety, public welfare and the environment contain both specific and general requirements. In addition to summarizing specific requirements, this document also provides guidance on what approaches the Department considers acceptable for meeting the general requirements set forth in the regulations. Parties using this guidance should be aware that there may be other acceptable alternatives to this guidance for achieving compliance with such general regulatory requirements.

The regulatory citations provided throughout this document are not meant to be, and should not be relied upon to be, a complete list of all the regulatory requirements for risk characterization. Parties undertaking a risk characterization for a site should consult 310 CMR 40.0000 (MCP) for applicable requirements.

This guidance document is intended for use by anyone conducting risk characterizations pursuant to Subpart I (310 CMR 40.0900) of the Massachusetts Contingency Plan (MCP), including those sites considered to be adequately regulated subject to other regulatory schemes pursuant to 310 CMR 40.0110 through 40.0114. In addition to persons conducting risk characterizations at sites, this material may also be of use to persons *reviewing* MCP risk characterizations, persons conducting a risk assessment for other (non-MCP) purposes, and the interested public. The Massachusetts Contingency Plan is a set of regulations for the notification, assessment and remediation of contaminated sites promulgated pursuant to M.G.L. Chapter 21E (c.21E), the Massachusetts Oil and Hazardous Materials Release Prevention and Response Act. The MCP, originally promulgated in 1987, was significantly rewritten in 1993 and 1994 to implement sweeping amendments made to c.21E in 1992. The new program strengthens and expands the role of the private sector and encourages those legally responsible for sites to conduct response actions in a timely way. In addition, the new MCP focuses limited governmental resources on the sites considered to present the greatest potential for harm to health and the environment, and on those tasks the public sector has to perform to ensure that private sector actions are appropriate.

A key feature of the new c.21E program is its reliance on **Hazardous Waste Site Cleanup Professionals** (also called "**Licensed Site Professionals**", or "**LSPs**") to oversee assessment and cleanup actions and to ensure that such actions are performed in compliance with the MCP. LSPs oversee and manage response actions and render opinions that response actions, *including the risk characterization portion of the response action*, meet the MCP's requirements. LSPs are licensed by the Commonwealth and employed by people conducting response actions. The regulations that establish the licensing process and criteria can be found in 309 CMR 1.00 - 8.00. A list of LSPs is available from the Board of Registration of Hazardous Waste Site Cleanup Professionals (telephone: 617-292-5556).

Risk characterization is used in the Massachusetts Contingency Plan to determine whether a remedial response action is necessary and to document that a level of no significant risk of harm to health, safety, public welfare and the environment exists or has been achieved for the site. In this context, the site risk characterization is a decision tool for making remedial decisions in a manner which is both protective of public health and the environment and consistent from site to site. A risk characterization must be performed at each site seeking a Response Action Outcome (RAO), because determining whether a condition of "*No Significant Risk*" exists is a basic requirement of an RAO.

Response Action Outcomes, or RAOs, are the end-points of all response actions conducted under the Massachusetts Contingency Plan, and the documentation that the disposal site has reached an end-point is the Response Action Outcome Statement. RAOs are divided into three main categories (A, B and C) and several subcategories (e.g., A-1, A-2 and A-3) to distinguish between the different types of end-points which may be reached for a given site. Only a Class A-1 RAO, which applies to sites that have been cleaned up to background levels, can be achieved without conducting a quantitative risk assessment. To achieve any other RAO, a risk assessment must be conducted.

While risk characterizations may be performed at any point during the site assessment and remediation process (assuming that sufficient information about the site and the contamination has been gathered) they are typically conducted at two points in the process: (1) as part of a site assessment, to determine whether or not remediation is necessary, and/or (2) following a remedial response action to determine whether the action effectively eliminated significant risk.

The general data gathering and interpretation which must precede the risk characterization is described in the regulations beginning at 310 CMR 40.0904. These activities include investigation of the physical characteristics of the site; identification of the source and extent of the release; characterization of the type, volume, nature, etc. of the released oil or hazardous materials (OHM); identification of applicable soil and groundwater categories; identification of exposure points and the concentration of OHM at these exposure points; and identification of background levels of OHM. While it is beyond the scope of this document

to provide detailed guidance on all site investigation activities, **Section 2.0: Site Characterization** provides a discussion of those issues which have the greatest potential impact on the risk characterization process.

*The scope and level of effort of the risk characterization depends upon the complexity of the disposal site and the response action being performed. A Licensed Site Professional may provide technical justification (310 CMR 40.0193) for forgoing specific site investigation activities if, in his or her professional judgement, any particular requirement is unnecessary or inappropriate based upon the conditions and characteristics of the site. The LSP must employ RAPS (Response Action Management Approach, 310 CMR 40.0191) in determining whether any such activity is unnecessary or inappropriate.*

Having collected sufficient site information, the risks of harm to health, safety, public welfare and the environment must be evaluated (or characterized). As described in 310 CMR 40.0940 of the MCP, risks of harm to health, public welfare and the environment must be characterized by one of three methods. The Massachusetts

Contingency Plan describes these three methods of risk characterization, and this document includes guidance for all three approaches. *In general, only one method should be used for a given disposal site*, although there are circumstances when a combined approach is appropriate. Guidance for selecting the appropriate risk characterization method is contained in **Section 3: Selection of Risk Characterization Method**. Correct choice of the appropriate method is extremely important. Note that the risk of harm to safety is evaluated in the same manner at all sites, no matter which method is used to characterize the risks to health, public welfare and the environment. Guidance on evaluating risk of harm to safety is provided in **Section 4.0: Characterization of Risk to Safety**.

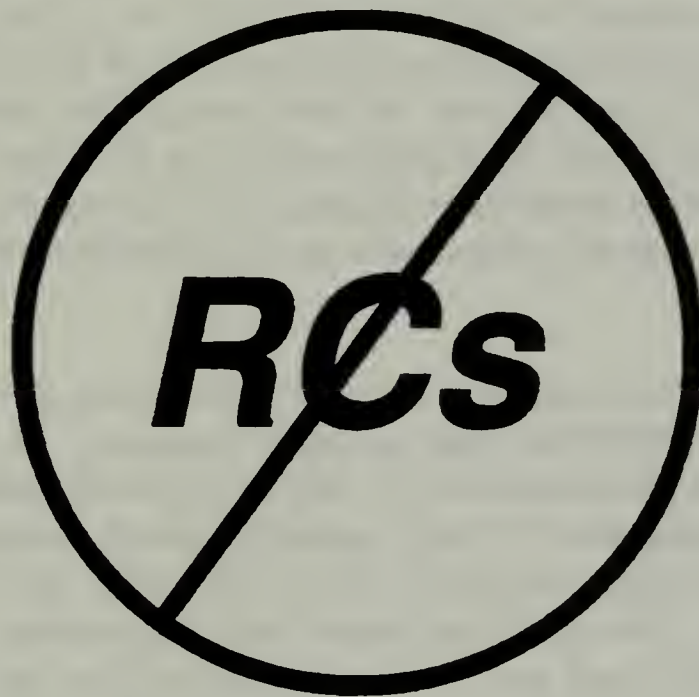
Method 1 risk characterizations (described in the MCP at 310 CMR 40.0970 and in **Section 5.0: Method 1** of this document) compare promulgated lists of soil and groundwater standards to contaminant concentrations detected at the site. Method 2 assessments (310 CMR 40.0980) allow for limited modification of the Method 1 standards based upon site and chemical-specific fate and transport factors. In addition, if MADEP has not promulgated a Method 1 soil or groundwater standard for a chemical, Method 2 may be used to develop values analogous to Method 1 Standards. The use of Method 2 is described in **Section 6.0: Method 2** of this document. Method 3 risk characterizations employ site-specific information (particularly the potential for exposure to contaminants) to independently evaluate the risks of harm to health, public welfare and the environment. The recommended procedures for the evaluation of human health risks are described in **Section 7.0: Method 3 - Human Health**, while the procedures for characterizing the risk of harm to public welfare and the environment are presented in **Section 8.0: Method 3 - Public Welfare** and **Section 9.0: Method 3 - Environmental Risk Characterization**.

There are some site conditions which warrant immediate attention, including early notification to MADEP and the implementation of an **Immediate Response Action (IRA)**.

Immediate Response Actions must be undertaken to address sudden releases of oil or hazardous material, **Imminent Hazards** and other time-critical conditions identified in the MCP (310 CMR 40.0410). **Section 10.0: Imminent Hazard Evaluations** describes the process by which site conditions may be assessed to determine whether or not an Imminent Hazard exists.

Additional guidance is provided in the Appendices. Appendix A presents a glossary of terms and acronyms used in the MCP and this guidance document. Appendix B presents suggested default assumptions which can be used to estimate site exposures. Appendix C contains a discussion of the use of probabilistic techniques to characterize risk under the MCP. Appendix D presents guidance on fish tissue sampling. Appendix E provides references for potentially Applicable or Suitably Analogous Standards. Appendices F and G contain outlines of the basic components of Method 1 and Method 2 Risk Characterizations, while Appendix H presents guidance for preparing a Method 3 Scope of Work.

## The Misuse of Reportable Concentrations (RCs)



### in MCP Risk Characterizations

**Reportable Concentrations are ONLY triggers for notification** under the Massachusetts Contingency Plan and any other use of those numbers is not sanctioned by the Massachusetts Department of Environmental Protection.

**Reportable Concentrations are NOT cleanup standards.** The MCP Method 1 Standards are a distinct and separate list of numbers and their use is described in detail in Subpart I of the MCP and Section 5.0 of this document.

**Reportable Concentrations are NOT "No Risk" levels.** Sites with concentrations of oil or hazardous material below RCs do not trigger notification to MADEP *at that time* but may pose significant risk and require remediation. Information gathered at a later date or through the DEP's Site Discovery Program may result in the need for notification and/or remediation.

**Reportable Concentrations are NOT screens to eliminate Contaminants of Concern from a risk assessment.** The acceptable approach for eliminating chemicals from further consideration is discussed in Section 2.4 of this document.



## THE UNIVERSITY OF CHICAGO

The University of Chicago is a private research university in Chicago, Illinois. It was founded in 1837 and is one of the oldest and most prestigious universities in the United States.

The university is known for its commitment to academic excellence and its diverse student body. It has a long history of producing world-class scholars and leaders in various fields of study.

The University of Chicago is a member of the Association of American Universities and is ranked among the top universities in the world. It has a strong reputation for its research and its commitment to public service.

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## 1.0 PURPOSES OF RISK CHARACTERIZATION IN THE MCP

As described in Subpart I of the Massachusetts Contingency Plan (MCP), risk characterization is used in the Waste Site Cleanup Program to determine whether a remedial response action is necessary at disposal sites, to identify target cleanup levels in the event that a remedial action is required and to document that a level of no significant risk of harm to health, safety, public welfare and the environment<sup>1</sup> exists or has been achieved for a site. In other words, risk characterization is used to answer the question *"How Clean is Clean Enough?"*

In this context, the site risk characterization is a decision making tool with which remedial decisions may be made in a manner which is both protective of public health and the environment and consistent from site to site. A risk characterization must be performed at each site seeking a Response Action Outcome (RAO): a condition of *"No Significant Risk"* is a basic requirement of an RAO. While risk characterizations may be performed at any point during the site assessment and remediation process (assuming that sufficient information about the site and the contamination has been gathered) they are typically conducted at two points in the process: (1) following a comprehensive site assessment to determine whether or not remediation is necessary, and (2) following a remedial response action to determine whether the action effectively eliminated significant risk.

While the terms "Risk Characterization" and "Risk Assessment" are often used synonymously, there is a subtle difference in their meaning in the regulations. A risk assessment describes, often quantitatively, the potential risks, answering the question, *"What are the risks associated with the contamination at this site?"* An MCP Risk Characterization takes the process one step further: using criteria promulgated in the regulations, the risk characterization answers the question, *"Are those risks significant (important)?"* The standards used to answer that question may be expressed qualitatively, as concentration-based standards or as limits on Cumulative Receptor Risk, depending upon the nature of the risks being evaluated and the risk characterization approach used. Each report presenting an MCP Subpart I Risk Characterization must contain both the documentation of the risk assessment and a clear statement whether or not a condition of no significant risk of harm to health, safety, public welfare and the environment exists or has been achieved. Thus Risk Characterization is a process which combines both risk assessment and risk management.

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<sup>1</sup> In this document, the capitalized term "No Significant Risk" is often used in lieu of the longer "no significant risk of harm to health, safety, public welfare and the environment." Reference to single measures, such as "no significant risk to the environment," will not use the capitalized form.

## 1.1 DEMONSTRATE NEED FOR A RESPONSE ACTION

A tanker truck overturns on Route 128, spilling gasoline across the highway and into a drainage ditch. *Is a response action necessary?* At many sites regulated under the Massachusetts Contingency Plan the answer is intuitive: it is obvious to the owner/operator, the site manager overseeing the assessment/remediation and to the government regulators involved that remediation must take place. Like this example, many MCP sites result from the sudden release of oil or hazardous material (OHM) and Emergency Response teams are called in immediately to clean up the spill, often to "background" levels.

Unfortunately, the question of whether remediation is necessary is not always so clear. The decision about whether the conditions at a site are serious enough to require remediation requires evaluation of a number of factors such as the possible presence of ongoing releases, the use of the site, the location of the contamination and the concentrations of the oil or hazardous material. One of the primary purposes of promulgating the MCP was to establish a consistent set of rules by which decisions about the need for remedial action could be made. Risk Characterization is one of the tools incorporated into the regulations to assist site managers in making decisions that are both consistent from site to site and protective of health, safety, public welfare and the environment.

### 1.1.1 Baseline Risk Characterizations

A "baseline" is a measure used as a standard for comparison. In environmental regulation, a baseline measure describes the conditions which would exist in the absence of any controls or remedial measures - in other words, the baseline measure describes the "No Action" alternative. Thus, a baseline Risk Characterization describes the health, safety, public welfare and environmental risks which would exist if no remedial actions were taken to address the contamination at a disposal site. Because a baseline risk characterization assumes that no remedial action will take place, the assessment includes an evaluation of both current and future exposures to the unremediated contamination.

At most sites, however, a true baseline risk characterization may never be carried out. The 1993-1994 revisions to the MCP allow preliminary response actions and risk reduction measures to be taken without a formal determination that the contamination at the site poses significant risk. This change was made to the regulations in response to comments that the need for action (and the appropriate type of action) at a site is often evident, and resources should be spent on actually cleaning up sites and reducing risk rather than documenting the need to take such actions. Thus, the first, and only, risk characterization performed for a c.21E site may be to demonstrate that the remedial actions already implemented have achieved a condition of No Significant Risk. In other

words, such risk characterizations describe the "No Further Action" alternative<sup>2</sup>. (The assumption that no further remedial action will take place means that future exposures to any residual contamination must be addressed.) While this approach can greatly streamline the assessment/remediation process, there are potential problems as well. Without an adequate understanding of the site, chemical concentrations and exposure pathways, the initial remedial measures may not be sufficient to achieve a level of No Significant Risk, and further response actions may be necessary. Risk characterizations conducted before a remedial measure is carried out can be used to plan cost effective remedial strategies, such as targeting for cleanup those chemicals or exposure media contributing the most risk.

The Risk Characterizations submitted to MADEP to support a Response Action Outcome Statement for a site may be either a baseline or modified baseline evaluation, and the guidance which follows does not distinguish between the two. The difference is only important in so far as the type of RAO (Class A or B) depends upon whether or not a response action has been implemented at the site (310 CMR 40.1035 and 40.1045).

### 1.1.2 Imminent Hazard Evaluations

Imminent Hazard Evaluations are a specific type of MCP risk characterization which answers the question, "*Is a remedial action required NOW?*". It is a form of baseline risk assessment which typically evaluates the potential risks associated with short-term exposures at a site under current conditions. Imminent Hazard Evaluations are not required at all sites, but are triggered by the presence of conditions indicating the potential for an Imminent Hazard. An Imminent Hazard Evaluation should be conducted whenever information indicating a potential imminent hazard comes to light, which could be at any point in the site assessment/remediation process. Section 10 of this document describes when and how such evaluations are conducted.

### 1.1.3 Identification of Target Cleanup Levels

When a risk characterization indicates that remediation is needed (i.e., a condition of No Significant Risk has not been achieved) the question "*Is a response action necessary?*" becomes "*When can the response action stop?*" In much the same way that the question is turned around, the risk characterization can be reversed and used to identify target cleanup levels. The equations used to estimate exposure and risk (Sections 7.3 and 7.4) can be applied to combinations of chemical and medium-specific concentrations which would meet the Method 3 Cumulative Risk Limits. (At a given site, there may be an

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<sup>2</sup> This type of post-remedial action assessment could be thought of as a modified Baseline Risk Characterization, "modified" because the remedial measure has altered the initial conditions (changed the baseline.)

infinite number of combinations which could meet the Method 3 Cumulative Risk Limits, and risk assessment can be used to identify target cleanup levels which maximizes risk reduction and minimizes cost.) The standards promulgated in Method 1 (310 CMR 40.0970), which indicate the need for remediation when exceeded, can also be used as target cleanup levels during remediation, as can Method 2 Standards.

#### **1.1.4 Evaluation of Remedial Alternatives**

When remedial alternatives utilizing known technologies are proposed, it is often possible to project the effectiveness of those technologies in reducing contaminant concentrations (and thus exposure point concentrations.) When the capabilities of a given technology are described in terms of likely residual concentrations, then a risk characterization can be performed to determine if that technology is capable of achieving a condition of No Significant Risk at the site. If there is more than one remedial alternative being considered, then the relative effectiveness (particularly the cost effectiveness) of the technologies in reducing risk may be an important factor in choosing among the alternatives.

### **1.2 RISK CHARACTERIZATION & RESPONSE ACTION OUTCOME (RAO) STATEMENTS**

The relevance of risk assessments to Response Action Outcomes is discussed in the Introduction Section, and the regulations specific to Response Action Outcomes (or RAOs) are located in Subpart J (310 CMR 40.1000) of the MCP. This guidance document focuses on *one* of the minimum requirements of a Response Action Outcome: the risk characterization (310 CMR 40.1004(1)(a)). It does *not* present detailed guidance on all of the requirements and procedures for RAOs. The reader is referred to the MCP itself and guidance on a range of topics issued by MADEP (e.g., the MCP Q&A publications) for additional information.

The *Response Action Outcome Statement & Downgradient Property Status Transmittal Form* (BWSC-104) is the form which must be submitted to MADEP along with the documentation which supports the Response Action Outcome. The form itself and written guidance on completing the form are available from MADEP, through the Regional Service Centers and the Infoline.

The general requirements (310 CMR 40.1003 and 40.1020) for achieving a Response Action Outcome include:

- A level of No Significant Risk must exist or have been achieved (Class A and Class B RAOs);
- Achieving an RAO and the submitting an RAO Statement must occur within the deadlines established by the MCP or by the Department;
- An RAO may be achieved and an RAO Statement submitted for any site, disposal site or portion of a disposal site;
- The boundaries of a site or portion of a disposal site to which the RAO is applicable must be clearly and accurately delineated;
- Each source of oil or hazardous material must be eliminated or controlled (for Class A and Class B RAOs); and
- Where feasible, at any disposal site or portion of a disposal site where a remedial action is taken to achieve a Permanent Solution, such actions must achieve or approach background levels of oil or hazardous material.

**It is important to note that achieving a level of No Significant Risk is just one of several requirements: it should be thought of as a minimum requirement, not the only requirement. Even after a level of No Significant Risk has been achieved, further actions may be necessary to eliminate continuing sources of oil or hazardous material to the environment or to achieve/approach background levels.**

Risk assessors and site managers should not focus on the results of the risk assessment to the exclusion of the other requirements of the RAO. A cost effective approach to site management and remediation would ensure that all of the requirements of a Response Action Outcome are considered early in the planning of remedial strategies.

### 1.3 LEVEL OF EFFORT APPROPRIATE TO THE ACTION TAKEN

Response Action Outcomes may be achieved at any time during the MCP process, from the time of notification to the end of Phase V Operation, Maintenance and Monitoring<sup>3</sup>. The timing of the RAO will depend upon the nature and extent of release and other site-specific factors. In order to achieve an RAO, the RAO Statement must be submitted with evaluations and assessments of sufficient scope and detail to support the conclusion that all the applicable MCP requirements have been met. Recognizing that the scope, detail and level of effort necessary to meet the MCP requirements may vary from site to site, many of the requirements of the regulations are written in terms of Performance Standards rather than laying out specific events which must occur. The performance standards for Response Action Outcomes are listed at 310 CMR 40.1004. The overall performance standard, known as the Response Action Performance Standard (RAPS), for work conducted under the MCP is given at 310 CMR 40.0191. Provision is also made for exercising professional judgement to forgo certain site assessment activities based upon technical justification (310 CMR 40.0193.)

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<sup>3</sup> The regulations (310 CMR 40.0801 and 40.0810) outline five phases of Comprehensive Response Actions conducted pursuant to the MCP: (a) Phase I Initial Site Investigation, (b) Phase II Comprehensive Site Assessment, (c) Phase III Identification and Selection of Comprehensive Remedial Alternatives, (d) Phase IV Implementation of the Selected Remedial Action Alternative, and (e) Phase V Operation, Maintenance and/or Monitoring.

## 2.0 SITE CHARACTERIZATION

### 2.1 CURRENT AND FORESEEABLE USE

This section of the *Guidance for Disposal Site Risk Characterization* describes the role that site use plays in the characterization of risk under the MCP requirements. Topics which are covered include issues to consider in determining the current and the reasonably foreseeable uses of the site and the surrounding environment, how limitations may be placed on the foreseeable use in order to limit the scope of the risk characterization and remediation, and the soil and groundwater categories established by MADEP as measures of site use.

The risk characterization methods of the MCP are used to establish whether a level of No Significant Risk exists or has been achieved at a disposal site for *any current or reasonably foreseeable uses of the site and surrounding area*. The use of a site and surrounding area determines the activities which occur there and the potential for exposures which could occur there, consistent with the site use. In order to adequately evaluate exposures, the risk characterization must identify and describe the site activities and uses associated with the disposal site and surrounding environment (40.0923). The requirement to consider site use (both current and foreseeable) comes from the definition of "no significant risk" found in M.G.L. c.21E 3A(g). The risk assessment should address all current and reasonably foreseeable uses and activities at the disposal site or in the surrounding environment which could result in exposure to oil and/or hazardous material by human or environmental receptors (40.0923 (1)).

In this document the terms "activity" and "use" are both employed to describe human or environmental pursuits which could result in exposure to human or environmental receptors. As used here, "use" usually refers to the property itself and is generally a broader term than "activity", which is used here to describe actions by a receptor which could potentially result in exposure. Zoning terms, such as "residential", "commercial" and "industrial" are helpful but incomplete descriptors of exposure potential.

Knowledge about the current and foreseeable uses of the site is necessary to identify exposure points and exposure pathways and to classify soil and groundwater. The exposures to be evaluated in a human health or environmental risk assessment depend upon the activities which could occur under the current and foreseeable uses of the land and groundwater at the site.

The MCP recognizes a distinction between the current use of the site and the foreseeable use. "*Current*" is actual or possible given current circumstances, while "*foreseeable*" has not yet occurred, is hypothetical and may yet be changed or avoided. Current uses and activities

must be identified and evaluated to be protective of present receptors, and reasonably foreseeable uses and activities must be identified to be protective against potential future exposures which could occur if no action were taken at the disposal site.

### 2.1.1 Current Site Activities and Uses

Any current site activities and uses that could result in exposure of human and/or environmental (plants, animals and their habitats) receptors must be described in the risk assessment. The current *use* (again, *use* is the broader term) of the site may be consistent with a wide range of site *activities* (*activity* is the narrower term), some of which may happen to be occurring at the time of the risk assessment, but all of which should be identified and assessed as a current activity. For example, if a disposal site with soil contamination is currently used as residential property, the risk assessment should evaluate exposures to children having contact with the soil, regardless of the age of the present residents. The MCP requires that activities which are not occurring at the time of the assessment, but are consistent with the current use of the site, must be evaluated (310 CMR 40.0923(2)).

### 2.1.2 Reasonably Foreseeable Activities and Uses

The reasonably foreseeable activities and uses should include any possible future activity or use (310 CMR 40.0923(3)), with some important exceptions described below. These foreseeable uses must be evaluated in the risk assessment if they would result in greater human or environmental exposures than the current site use: in other words, since the current site use must be evaluated, there is little need to evaluate foreseeable uses which would result in less exposure. (This is an important point in streamlining the risk assessment process, since there are theoretically innumerable possible exposure scenarios. For a given site the risk assessor should quantify the risks only for the most exposed receptors and conclude that receptors experiencing similar exposures but to a lesser degree would face lesser risks than those estimated.)

One of the exceptions to the "*anything is foreseeable*" rule is drinking water. It should not be assumed that all groundwater is a foreseeable source of drinking water. In determining whether or not the foreseeable use of site groundwater is drinking water, the MADEP criteria listed at 310 CMR 40.0932(4) must be used. These criteria were developed by the Commonwealth of Massachusetts for the protection of its groundwater resources. By these criteria, groundwater which is either a current or potential future source of drinking water is categorized as GW-1 and must be protected for this use. Except as described in those criteria there are no site-by-site exceptions, nor can professional judgement be used to overrule the criteria. The GW-1 criteria are discussed in more detail below.

Another exception to the "*anything is foreseeable*" rule is that the owner of a property may rule out any hypothetical future site use or activity for that property through an Activity and Use Limitation (AUL). AULs are discussed in more detail below. For example, if the present use of a disposal site is commercial with activities which pose limited exposure potential for children, receptor exposures would be evaluated based upon this commercial use/activity scenario. Exposures evaluated for the future use of the property would include foreseeable residential use with associated activities (including those for children) *unless* an AUL is implemented to restrict land use. One possible outcome would be the application of an AUL to ensure that the future use(s) and activities for the property remain consistent with the current use, in which case the current exposures would also be the future exposures.

**NOTE:** If the risk assessment is conducted prior to implementation of an AUL, but it assumes that certain exposures will be limited by the planned AUL, the risk assessment must clearly state the assumed exposure limitations, and that the results of the risk assessment will not be valid until the AULs are in place.

### 2.1.3 Activity and Use Limitations

Activity and Use Limitations (AULs) serve several purposes (310 CMR 40.1012(4)). First, they provide notice to future owners of a property, abutters, local officials and MADEP as to what uses and activities are consistent with a level of No Significant Risk at the site. Conversely, they describe conditions under which the site *may* pose a significant risk of harm, and the AUL establishes a duty to evaluate such conditions *prior to* any change in site use. Thus AULs are declarations of the acceptable and unacceptable uses and activities for a site; they are not intended to permanently restrict changes in site use as much as to ensure that any proposed changes are evaluated considering the residual contamination and any increased exposure likely to result from changes in use (310 CMR 40.1080).

An AUL may apply to an entire property, an entire site or to some portion of a property or site. AULs may be used to eliminate entire exposure pathways which would otherwise need to be considered in the evaluation of future site use.

When foreseeable exposures are excluded from a risk assessment because of an AUL, documentation and description of the AUL is a fundamental component of the risk assessment. In such cases the risk assessment is only valid when an adequate and appropriate AUL is in place. Basic issues regarding AUL implementation are presented in a Question and Answer Format.

*When would an AUL be used?*

- An AUL would be used anytime the risk characterization is performed assuming some restrictions on the use of the site or the activities which would occur there.
- An AUL may be used to limit the number of site uses and/or activities which would otherwise be evaluated as reasonably foreseeable, thereby reducing the scope of the risk characterization. The most common application of an AUL would be to limit the site use and activities to those which are currently occurring. Remediation goals which would achieve a level of No Significant Risk for the current site use would then be acceptable for the foreseeable future.

*When are AULs not necessary?*

An Activity and Use Limitation is not required if the site is acceptable for unrestricted use. This would include sites where:

- Levels of oil and hazard material are at or below background concentrations; or
- For sites characterized using Methods 1 or 2, the levels of OHM are at or below applicable category S-1 soil standards;
- For sites characterized using Method 3, no limitations on site use were assumed or implied in the risk characterization (e.g., residential use of the site, including unrestricted access to all soil, including soil at depth, is assumed and evaluated).
- residual contamination is located at a depth greater than 15 feet from the ground surface; or

Another situation that does not require an AUL is residual contamination located within a public way or within a rail right-of-way. These areas have been exempted as a matter of policy because the deeds are held differently than those for private property, and are less amenable to the application of AULs.

An AUL is also not required if the groundwater is determined not to be a current or foreseeable source of drinking water, based upon MADEP criteria. While this is a restricted-use scenario, the fact that the criteria used in this determination were developed by MADEP negates the need for an AUL.

An AUL is not required when under current conditions the GW-2 Standards are exceeded and the depth to groundwater is less than 15 feet, but there are no occupied structures on the site. In this situation, an AUL is not required to prevent any future construction

at the site. If however, construction were to occur at the site, the future conditions would have to address meeting the GW-2 Standards.

Finally, AULs are not required but may be used to provide notice of the existence of residual contamination at a disposal site where all substantial hazards have been eliminated and where all applicable requirements for a class C RAO have been met pursuant to 310 CMR 40.1050.

*Are there any limitations on the use of AULs?*

- A planned or proposed AUL may never be used to limit the current use/activities of a site. Note, however, that if an AUL is already in-place and effective, it is part of the current use of the site: any limitations on activity or use which it achieves can be considered in the risk assessment. For example, if a site is currently used as residential property, the risk assessment should evaluate exposures associated with gardening activities such as: direct contact with contaminated soil, incidental ingestion of soil and ingestion of vegetables grown in the soil. If, however, prior to the risk assessment a limitation was placed on the property identifying gardening as a prohibited activity, and that AUL is determined to be effective, then the risk assessment need not evaluate exposures from gardening. If no AUL is in place at the time of the risk assessment, gardening exposures must be evaluated whether or not gardening activities are currently occurring.

*Who may place the AUL on the disposal site?*

The property owner is the only individual who can limit site activities and uses through the use of an AUL. In addition, MADEP may impose an AUL at disposal sites where it has conducted response actions or at sites where the property owner fails to record or register an environmental restriction (see 310 CMR 40.1073).

Although the property owner is ultimately responsible for placing AUL on the site, the decision to use an AUL should be made in consultation with the risk assessor and the Licensed Site Professional (LSP) who can describe the costs and benefits of using this tool.

*What information should be included in the AUL?*

The contents of the AUL are specified in 310 CMR 40.1071(2) of the MCP. In 40.1071(2)(h) through (k), the regulations describe the risk-related information contained in an Activity and Use Limitation, including what uses and activities are prohibited on the property, conditions necessary to maintain a level of No Significant Risk, and a description of the permitted activity and uses.

The AUL must be very specific as to the portion of the disposal site subject to the use restrictions.

*How should an AUL be referenced in the risk assessment?*

The results of the risk assessment are based upon the exposure assumptions utilized in the process. The exposure assumptions in turn are based upon the current and foreseeable uses of the site. The conclusions of the risk assessment must therefore discuss all limitations in detail. When an AUL is placed on the disposal site, the risk assessment is only valid and applicable in conjunction with the AUL.

*What types of AULs exist under the MCP?*

The MCP at 310 CMR 40.1070 identifies two types of Activity and Use Limitations: an Environmental Restriction and a Notice of Activity and Use Limitation. The specific requirements for each type of limitation are delineated in the MCP. The technical requirements are somewhat different. The overall purpose of both limitations is, however, to describe the type of use and specific activities that will be allowed at the site, and those activities which are expressly forbidden.

- The general requirements of an Environmental Restriction are delineated in 310 CMR 40.1071 (1). The basic requirements include: submittal to the Department of an AUL Opinion from an LSP specifying the need for the AUL, the activities and uses permitted, prohibited or restricted, and any obligations or conditions necessary to maintain a level of no significant risk. The Grant of Environmental Restriction must be signed by the Commissioner and then recorded with the appropriate Registry of Deeds and/or Land Registration Office.
- The general requirements of the Notice of Activity And Use Limitation are found at 310 CMR 40.1074 (1). The basic requirements include: (1) submittal to the Department of an AUL Opinion with a Response Action Outcome (RAO) Statement specifying the need for the AUL, the activities and uses to be permitted, prohibited or restricted, and any obligations or conditions necessary to maintain a level of no significant risk, and (2) the property owner shall record and/or register any AUL Notice in the appropriate Registry of Deeds and/ or Land Registration Office and within 30 days thereof submit a certified copy to the Department.

*What are the Limits on the Use of AULs?*

The application of Activity and Use Limitations to a property depends upon the extent to which the property owner wishes to restrict the use of that property.

The application of these limitations to groundwater, however, is somewhat restricted. A groundwater aquifer is a State resource and therefore its foreseeable use is determined by the State and not by the individual property owner. As noted above, the determination of whether or not the groundwater is a drinking water resource (GW-1) is determined in accordance with the criteria listed in 310 CMR 40.0932(4). The only situation in which groundwater that has been classified as GW-1, may be subjected to an Activity and Use Limitation is when the groundwater is classified as GW-1 solely on the basis of the presence of private drinking water wells within 500 feet (310 CMR 40.0932(5)(d)). An Environmental Restriction (*not* a Notice of Activity and Use Limitation) may be applied to restrict the use of groundwater if and only if:

- the private wells are abandoned;
- the properties previously supplied with drinking water by those wells are tied into a public drinking water distribution system; and
- the affected property owners agree to place an Environmental Restriction on their property.

The properly executed Environmental Restriction must then be recorded. The restriction will serve to prohibit the placement of private wells or to reactivate closed wells on the property in the reasonably foreseeable future.

#### **2.1.4 Groundwater and Soil Categories**

The MCP establishes categories of groundwater and soil which should be utilized in characterizing risk posed by a disposal site. Groundwater and soil must be categorized when conducting a risk assessment regardless of the method selected. When utilizing either Method 1 or Method 2 it is necessary to categorize the soil and groundwater so that the appropriate soil and groundwater standards will be used. The groundwater and soil standards for Methods 1 and 2 are listed in 310 CMR 40.0974(2), 310 CMR 40.0975(6)(a)(b) and (c), and 310 CMR 40.0985(6). When conducting a Method 3 risk assessment the soil and groundwater categories should also be identified to aid in the development of exposure profiles and to identify applicable or suitably analogous standards as described in 310 CMR 40.0993(3). Finally, it is necessary to have categorized soil and groundwater prior to placement of any Activity or Use Limitations at the site. Specific guidance on the classification of soil and groundwater at a site is discussed below.

##### **2.1.4.1 Categorization of Groundwater**

The MCP identifies three types of applicable groundwater categories in 310 CMR 40.0932, which are described as GW-1, GW-2 and GW-3. These groundwater categories were established to identify groundwater associated with three distinct types of exposures: its use as drinking water, as a source of indoor air contamination, and as a source of surface

water contamination. Because these exposures of concern are not necessarily related to each other, they are not mutually exclusive: Groundwater may, at the same time, be used as drinking water, be a threat to indoor air and discharge to surface water, in which case it would be considered to be categories GW-1, GW-2 and GW-3.

*At any disposal site more than one groundwater category may be applicable within the aquifer.*

Note also that MADEP assumes that all groundwater eventually discharges into surface water, and thereby acts as a source of contamination to that water body. Since the GW-3 Standards are based upon this assumption, the GW-3 Standards are applicable everywhere.

*All groundwater is considered to be GW-3.*

In addition, there may be disposal sites where groundwater in one area is classified as one category and another area is classified as a different category, even though the groundwater in both areas is part of the same aquifer.

#### *Groundwater Category GW-1*

Groundwater GW-1 is considered to be either a current or future source of drinking water, and the MCP describes six criteria (310 CMR 40.0932(4)) which are used to identify aquifers which should be protected for this use. If it is determined that the groundwater at a site meets any one of these criteria, its current and foreseeable use must be described as being a source of drinking water. The criteria are:

- (a) the groundwater is within a Zone II;
- (b) the groundwater is within an Interim Wellhead Protection Area;
- (c) the groundwater is within a Potentially Productive Aquifer;
- (d) the groundwater is within the Zone A of a Class A Surface Water Body;
- (e) the groundwater is located five hundred (500) feet or more from a public water system distribution pipeline; or
- (f) the groundwater is located within five hundred (500) feet of a private water supply well that was in use at the time of notification pursuant to 310 CMR 40.0300 and was installed in conformance with any applicable laws, by-laws or regulations.

The terms used in the classification criteria above are defined at 310 CMR 40.0006(11) as follows:

- The Zone II is defined as "that area of an aquifer which contributes water to a well under the most severe pumping recharge conditions that can be realistically anticipated, as approved by the Department's Division of Water Supply pursuant to 310 CMR 22.00.
- The Interim Wellhead Protection Area (IWPA) is defined as meaning:
  - (1) with respect to public water supply wells and wellfields whose pumping rate is one hundred thousand (100,000) gallons per day or greater and for which the Department has not approved a hydrologically delineated Zone II, the one-half mile (2640') radius surrounding such well or wellfield; and
  - (2) with respect to public water supply wells and wellfields whose pumping rate is less than one hundred thousand (100,000) gallons per day and for which the Department has not approved a hydrologically delineated Zone II, the radius calculated by multiplying the maximum pumping rate in gallons per minute for such well or wellfield by thirty-two (32) and adding four hundred (400) feet thereto (i.e.  $IWPA = (32)(y) + (400)$ ; where  $y$  = pumping rate in gallons per minute.)
- A Potentially Productive Aquifer is defined as:
  - (a) all aquifers delineated by U.S. Geological Survey (USGS) as a high or medium yield aquifer, except for any portion of a high or medium yield aquifer's surface area that is located in a municipality with a population density equal to or greater than 4,400 persons per square mile (based on the most recent U.S. Census); and
  - (b) all aquifers located east of the Cape Cod Canal (Cape Cod), on the Elizabeth Islands, on Martha's Vineyard, or on Nantucket.

*Note (7/95): The Potentially Productive Aquifer (PPA) definition is currently under review. Revisions to the MCP related to PPA designation and GW-1 categorization will be finalized by the fall of 1995. Readers should be sure to consult the latest version of the regulations for changes in this area.*

- A public water supply is defined as "a source of water supply, including, but not limited to, primary, backup and emergency sources, utilized by a public water system." The terms "public water supply", "primary source", and "emergency source" are defined at 310 CMR 22.02.

- A private water supply is defined as " a well which is utilized by a private water system." The system provides for " piped water for human consumption which has fifteen (15) or less service connections or does not regularly serve an average of at least twenty-five (25) individuals daily at least 60 days of the year."

Note that there is some flexibility in the regulations to consider site-specific factors, but this flexibility is limited to the following conditions. The MCP describes particular situations in which the groundwater which normally would be classified as GW-1 may be otherwise classified. These situations are described at 310 CMR 40.0932 (5)(a)(b)(c)(d), and are summarized below.

- If the groundwater would be classified as GW-1 solely on the basis of the groundwater being located within an Interim Wellhead Protection Area, and it can be demonstrated that the groundwater is hydrologically downgradient of the public supply well, or cross gradient and outside the zone of contribution for the public well, or that a hydrogeologic barrier exists between the site and the supply well, then the groundwater need not be classified as GW-1.
- If the groundwater would be classified as GW-1 solely on the basis that it is located within a Potentially Productive Aquifer (PPA), it need not be classified as GW-1 if the regional or site characteristics meet MCP criteria for exclusion from GW-1. DEP is currently (7/95) revising the section of the MCP regarding portions of PPAs that need not be classified as GW-1. Readers should be sure to consult the latest version of the regulations for changes in this area.
- If the groundwater would be classified as GW-1 solely on the basis of the site being located greater than 500 feet from a public water supply distribution line, it need not be classified as such if any portion of the parcel or facility is within 500 feet of such a pipeline.
- Finally, if the groundwater at the site would be classified as GW-1 because the location is within 500 feet of a private well, it need not be so classified if specific requirements are met such as connecting the properties to a public water supply and registering an environmental restriction on the groundwater. (See the previous discussion of limits on use of AULs).

### *Groundwater Category GW-2*

Groundwater can also serve as a source of volatile contaminants to indoor air, and MADEP established a groundwater category to identify circumstances under which such an impact may be likely. Groundwater will be classified as GW-2 when it is located within thirty (30) feet of an occupied building or structure and the average annual depth to groundwater in the area is fifteen (15) feet or less. *Note that for certain chemicals (particularly chlorinated hydrocarbons) the GW-2 standards are more stringent than the GW-1 or GW-3 standards.*

### *Groundwater Category GW-3*

All groundwater in the Commonwealth is classified as GW-3. GW-3 standards are based upon discharge to surface water. All groundwater is deemed to ultimately discharge to surface water. *Note that for certain chemicals (some metals and pesticides) the GW-3 standards are more stringent than the GW-1 or GW-2 standards.*

#### **2.1.4.2 Categorization of Soil**

In accordance with the MCP 310 CMR 40.0933 soil at each disposal site must be categorized as either category S-1, S-2 or S-3. The soil categories are based upon the potential for exposure. Category S-1 is associated with the highest potential for exposure and Category S-3 is associated with the lowest potential for exposure. Sites which meet applicable S-2 or S-3, but not S-1, soil standards must implement an Activity and Use Limitation to ensure that the soil category does not change without further assessment/remediation.

When categorizing soil at a disposal site, it is important to note that the category is based upon several factors described below. Any particular disposal site may have more than one category of soil present at the same time.

The factors to be considered in categorizing the site soil include:

- 1) the type of **receptor** present at the disposal site;
- 2) the **frequency** of use;
- 3) the **intensity** of use; and
- 4) the **accessibility** of the soil.

Each of these factors is discussed briefly in the following paragraphs.

## Receptor

The type of receptor at the disposal site must be considered when determining the appropriate soil category. The receptor should be identified as a child or an adult. If both children and adults are present at the site then the soil should be categorized based upon whichever would result in the most stringent soil category (e.g., and if the adult's exposure is more intense, the soil should be categorized based upon the adult's exposures). The MCP defines a child at 40.0933(4)(a)(4) as an individual age 15 or under.

## Frequency

Frequency of exposure describes how often a receptor has access to or use of the disposal site. The frequency of use is addressed in the MCP at 40.0933 (4)(a) and is classified as either "high" or "low". When evaluating frequency the risk assessor should be considering how often a receptor comes to the disposal site, not how often the receptor comes into contact with contaminated soil (i.e., the frequency term would not be reduced if the contamination were located at depth - the depth of the soil in question is considered separately under "accessibility").

## Intensity

The intensity of use considers activities which may, by their nature, result in more contact with contaminated soil. Intensity should be classified as "high" or "low". High intensity activities, such as gardening, digging or recreational sports would result in a greater exposure to the soil. Low intensity activities, such as walking could still result in exposure to soil, but to a lesser degree.

## Accessibility

The accessibility of the soil relates to the depth of the contaminated soil and whether there is any covering of the soil, by paving, a building or clean soil cover. Soil is classified as either "accessible", "potentially accessible" or "isolated". The criteria for determining which classification is applicable to the soil are identified at 40.0933 (4)(c). Note that in determining that soil is either "potentially accessible" or "isolated" it is assumed that the soil will not become accessible (because no excavation is anticipated or it is assumed that the asphalt surface will remain intact), and these assumptions would be reinforced with an Activity and Use Limitation.

To assist in categorizing soil, a matrix is provided in the MCP at 40.0933(9). This Table is reproduced on the following page.

# SOIL CATEGORY SELECTION MATRIX - HUMAN EXPOSURE POTENTIAL

RECEPTOR CHARACTERISTICS						
	CHILDREN PRESENT			ADULTS <u>ONLY</u> PRESENT		
	<u>HIGH FREQUENCY</u>		<u>LOW FREQUENCY</u>	<u>HIGH FREQUENCY</u>		<u>LOW FREQUENCY</u>
	High Intensity	Low Intensity	High Intensity	High Intensity	Low Intensity	High Intensity
Accessibility ↓ of Soil ↓	CATEGORY S-1			CATEGORY S-2		
ACCESSIBLE (SURFICIAL) SOIL 0 <= 3' (unpaved)	CATEGORY S-1			CATEGORY S-2		
POTENTIALLY ACCESSIBLE SOIL 3 <= 15' (unpaved) or 0 <= 15' (paved)	CATEGORY S-2			CATEGORY S-3		
ISOLATED SUB-SURFACE SOILS > 15' or under the footprint of a building or permanent structure	CATEGORY S-3			CATEGORY S-3		
* - Category S-1 also applies to any accessible soil where the current or reasonably foreseeable use of the soil is for growing fruits and vegetables for human consumption.						

## 2.2 DETERMINING THE NATURE AND EXTENT OF CONTAMINATION

This section provides guidance on determining the nature, extent, distribution and severity of contamination for the purpose of assessing exposures at disposal sites. Exposure assessment is only one of the many purposes for which chemical data is collected at 21E sites. Other applications include delineating the extent of contamination, identifying contaminants, comparing site concentrations with background levels. These and other applications are discussed briefly in Section 2.2.2 to show how different types of data are used in site assessments and to put the data quality needs of the risk assessment into perspective. However, the emphasis in this chapter is on the data needed for the risk assessment itself.

This chapter is also limited to data on environmental contaminant concentrations. Other kinds of data are often used in risk assessments, particularly in evaluating plant and animal exposures. Examples of such parameters include the hardness of surface water and the organic carbon content of sediment. Such supplementary parameters are described in more detail in Section 9.0. This section applies primarily to chemical concentrations in environmental media, such as soil and groundwater.

The Massachusetts Contingency Plan (MCP) sets investigation and cleanup requirements in terms of a general performance standard, rather than detailed procedural directives. The performance standard is referred to as Response Action Performance Standard (RAPS). The MCP (310 CMR 40.0191(1)) states that the Response Action Performance Standard is the level of diligence reasonably necessary to obtain the quantity and quality of information adequate to assess a site and evaluate remedial action alternatives, and to design and implement specific remedial actions at a disposal site to achieve a level of No Significant Risk....". Thus, the investigation and cleanup measures may vary from site to site, but in each case they must be sufficient to meet the goal of determining and achieving a condition of "No Significant Risk".

### 2.2.1 Data Quality Considerations

A comprehensive discussion of data quality issues and criteria is presented in EPA's *Guidance for Data Useability in Risk Assessments* (subsequently referred to as the *Useability Guidance*). Although that document was written for remedial investigations at Federal Superfund Sites, the principles of data quality evaluation contained in it are broadly applicable. Data quality considerations should underpin the development of sampling plans and the selection of analytical methods for all MCP site investigations.

Much of this section is taken directly from the *Useability Guidance*. That guidance outlines criteria that can be used to evaluate the adequacy and applicability of data in a risk assessment. The data quality criteria include:

## **Data Sources**

Data from various sources may be used in a typical site investigation. Examples of sources of analytical data are: (1) **Fixed (stationary) laboratory analyses**, which provide detailed information for a wide range of analytes, and are critical to quantitative risk assessment and site characterization, (2) **Field laboratory analyses**, which are performed using instruments and procedures equivalent to fixed laboratory analyses, and can provide defensible data if equivalent quality control procedures are implemented, and (3) **Field screening techniques**, which are usually performed to provide a preliminary estimate of the type and concentration of chemicals of concern. Different labs may also be considered different sources. Data sources must be comparable for data to be combined for use in quantitative risk assessment.

## **Documentation**

Sampling and analysis procedures must be documented thoroughly and accurately in order to verify that the analysis was conducted as reported, and that the data are reliable. Four types of documentation generally produced in support of analytical data are:

- Sampling and analysis and quality assurance plans;
- Standard operating procedures, the use of which assures consistency in sampling and analysis and reduces the level of error associated with data collection;
- Field analytical records which document the analytical procedures and quality assurance measures used in field analysis, as well as the data obtained from such projects. (Note: fixed laboratory analytical records are normally maintained by the labs themselves, and are not generally reproduced for individual projects unless requested);
- Chain of custody records, which establish the history and handling of each sample from collection to analysis. Chain of custody reports do not affect the quantitative estimates of risk, but provide some of the information necessary for all interested parties to have confidence in the data and the risk estimate.

## **Analytical Methods and Detection Limits**

The term detection limit is often used without qualification, but it is a very general term. There are several methods of calculating the detection limit, and the method

used in the risk assessment should always be specified in the report. Types of detection limits include:

- Instrument detection limit (IDL) includes only the instrument portion of detection, not sample preparation, concentration/dilution factors, or method specific parameters;
- Method detection limit (MDL) is the minimum amount of an analyte that can be routinely identified using a specific method;
- Sample quantitation limit (SQL) is the MDL adjusted to reflect sample-specific action, such as dilution or use of a smaller sample aliquot for analysis due to matrix effects the high concentration of some analytes;
- Practical quantitation limit (PQL) is defined in the SW846 Methods and is the lowest level that can be reliably achieved within specified limits of precision and accuracy during laboratory operating conditions.

The project manager should specify to the laboratory what type of detection limits are to be reported. **The sample quantitation limit (SQL) should be reported whenever possible.** The SQL is the *actual* detection limit for the specific sample and analysis being reported. The MDL or PQL, which are reported more often, are typical values for the method, but may not represent the actual detection limit for the analysis under consideration.

For the risk assessment, analytical methods with detection limits well below concentrations of potential concern should be selected. When chemicals are reported at concentrations near the detection limit, the data have a greater possibility of containing false negative and false positive results. If detection limits of conventional methods are near concentrations of concern for the chemical(s) being evaluated, then an analytical chemist should be consulted to assist in identifying alternative methods. The Useability Guidance presents a comprehensive discussion of the possibility of false positive or false negative results when the confidence limits of the detection limits overlap or fall above the confidence limits of the concentrations of concern.

### **Data Quality Indicators**

Data quality indicators provide quantitative measures of data quality. Those suggested in the EPA *Useability Guidance* are summarized below:

Completeness - indicates whether the range of contaminant concentrations, the suite of contaminants detected and the extent of contamination in environmental media at the site are fully represented in the data set;

Comparability - relates to whether data sets from different sources or different time periods are equivalent;

Representativeness - refers to the extent to which the data used to estimate exposure point concentrations define the true nature, extent and concentrations of the contaminants of concern to which receptors may be exposed;

Precision - is a measure of data variability introduced by measurement error, which is governed by a combination of sample collection and analytical factors;

Accuracy - provides a measure of the closeness of the reported concentration to the true value.

Each of these indicators has different meanings for sampling than for analysis. A comprehensive discussion of the implications of each indicator is presented in the EPA *Useability Guidance*. The quality of data with respect to these indicators is an important factor in determining its useability for risk assessment purposes.

## **2.2.2 Selection of Analytical Methods**

### **Analytical Methods and Procedures**

The precision, accuracy and sensitivity of different analytical procedures vary widely. Furthermore, some laboratory settings are more amenable than others to implementing and documenting rigorous quality assurance/quality control (QA/QC) procedures. Analytical procedures can be divided into 3 general categories: (1) procedures conducted in commercial fixed (stationary) laboratories, under established quality assurance programs, with well documented QA/QC procedures, using published analytical protocols; (2) procedures conducted in field (mobile or temporary) laboratories, using the same equipment and protocols as are employed in fixed laboratories; and (3) field screening techniques, which generally involve compromises in analytical procedure and overall data quality. This differentiation is useful for the purposes of this document, but is not a universally accepted categorization.

Under these definitions, field laboratory procedures are essentially equivalent to fixed laboratory methods with respect to analytical methods, equipment and conditions, sample preparation, QA plan and QC procedure, and documentation of QA/QC procedures, operating conditions and personnel qualifications. Although there are exceptions, data

from analyses done in commercial (fixed) laboratories are usually preferable to data from field labs because the latter generally do not operate within an established quality assurance program. As a result, extensive project-specific quality assurance documentation and review is needed to demonstrate equivalency with fixed lab data. (Note that under this definition, most of the gas chromatography work that is currently conducted in the field falls into the screening category, and is not considered field analysis.)

Compared with protocols carried out in fixed or field laboratories, screening methods involve some procedural compromises or shortcuts. One example of such a shortcut is using measurements of concentrations in one medium to estimate concentrations in a different medium, as is done in headspace screening of contaminated groundwater or soil. Another shortcut is the use of sample preparation/extraction techniques that are less rigorous than those followed in a laboratory. One very common compromise is the use of simple instrumentation that does not produce substance specific results, for example organic vapor analyzers. Such techniques save either time or money or both, but lead to compromises in overall data quality.

**The Massachusetts Contingency Plan clearly supports the use of professional judgement in selecting the analytical method most appropriate for a specific purpose.** In Section 310 CMR 40.0017, the MCP states:

*Procedures and methodologies employed for the collection and analysis of ... samples shall consist of:*

- (1) methods published by the Department, EPA...*
- (2) modification of published methods...*
- (3) unpublished methods, including screening methods, provided that such methods are scientifically valid and are of known and demonstrated level of precision, accuracy and are completely described and documented in response action submittals.*

When faced with a choice of potentially applicable analytical methods (for example the 500 or 600 series methods for groundwater analysis), project managers should exercise professional judgement consistent with the RAPS provisions of the MCP in selecting the appropriate method. Cost is an important factor, but it should not be the primary consideration. Above all, the quality of the data must be adequate for the specific purposes for which it will be used.

With respect to data quality indicators listed in the preceding section, field screening methods can differ substantially from fixed or field laboratory procedures. Screening procedures often produce data of adequate quality with respect to only a limited number of data indicators. However, **not all of the listed data quality indicators are relevant to every decision point in a site assessment.** Although the overall quality

of data from a screening method may be compromised, these data may nevertheless be of adequate quality and provide the information needed for some purposes.

In addition to differences in data quality indicators, **screening techniques often differ from fixed and field laboratory procedures in sensitivity and specificity.** Specificity is the ability of the technique to differentiate between a certain substance and other similar chemicals. Sensitivity is the ability of the technique to detect contaminants at the lower end of the range of concentrations of concern, and is expressed by the detection limit.

The most important factors to consider in determining the applicability of data from a particular screening technique are:

- \* Sensitivity
- \* Specificity
- \* Comparability
- \* Precision
- \* Accuracy

The factors on this list will be referred to as "data quality characteristics" throughout the remainder of this document. **The applicability of screening data at a particular decision point depends on the match between the data quality characteristics of the screening data in question and those that are relevant to the decision point of concern.** The following paragraph describes the disposal site decisions for which analytical data are used. For different decisions, the relevant data quality indicators and data quality characteristics may vary.

### **Site Assessment Decisions**

In the site assessment process, there are several decision points, or assessment components, where data are applied. These include:

- (1) determining the presence or absence of contamination at a site or a portion of a site; delineating the extent of contamination;
- (2) identifying the contaminants present;
- (3) comparing site concentrations with background concentrations;
- (4) deciding where to focus sampling efforts;
- (5) estimating exposure point concentrations;
- (6) monitoring remediation processes; and
- (7) verifying remediation effectiveness.

Each of the first three decision points listed above are basic components of the risk assessment in that they define and limit the scope. For example, the determination of where contamination is present and absent (delineating the extent of contamination) is a basic component of the exposure assessment. Although such decisions are often thought of as being separate from the risk assessment, the validity of the risk assessment depends in part upon correctly identifying and delineating the extent or the contamination.

The fifth decision point listed here, estimating exposure point concentrations, is more commonly thought of as *the* decision point that relates site investigation activities to the risk assessment. In principle it is no more important than determining the presence or absence or delineating the extent of contamination. Nevertheless, as discussed in the following section, the data quality requirements for estimating exposure point concentrations are generally more stringent than for some of the other site assessment decisions.

### **Applicability of Screening Data to Site Assessment Decisions**

To decide whether a specific screening method is a technically sound approach at any point in a site assessment, one has to think about exactly what kind of information is needed to answer the specific question. The assessor must determine whether the data quality characteristics of the screening data match the data quality needs for the decision point in question.

By definition, every screening method has certain limitations relative to standard laboratory techniques. If the limitations of a proposed screening method are not relevant to the question at hand, then the screening data are *effectively equivalent to lab data for the purpose in question*.

For example, suppose that data were needed to determine the bounds of the area contaminated by specific substances. From a regulatory perspective, the most important data quality characteristics are analytical sensitivity to the contaminants of potential concern. The detection limit of the selected method should be lower than the lowest concentration of concern, so that the probability of false negatives is decreased. The precision should be good enough so that analytical variability does not produce false negatives for sampling locations where the concentration is actually substantially higher than the detection limit. A screening procedure that is sufficiently sensitive and precise should provide data essentially equivalent to commercial laboratory data for the purpose of determining where the contamination is present and where it is absent. For some contaminants at some sites, depending on the extent and reliability of site history information, characteristics such as specificity, comparability, and accuracy may not be important considerations for determining the presence or absence of a contaminant. The

problem of delineating the extent of a release is similar to determining the presence or absence of contamination, and the same considerations apply.

From MADEP's viewpoint, screening methods are frequently useful (supplementing fixed lab data) at decision points related to *delineation* of contamination, but seldom applicable for decisions related to *characterization* of contamination. MADEP considers all of the data quality characteristics listed in the preceding section relevant to characterizing contamination, while a more limited subset of data quality characteristics may be relevant for delineating contaminated areas. Two of the decision points presented in the preceding section, *estimating exposure point concentrations* and *comparing site concentrations to background levels*, always require complete characterization of contamination; therefore these determinations cannot be accomplished using screening techniques. In general, **MADEP considers screening techniques not applicable to the estimation of exposure point concentrations or to the comparison of site concentrations to background.**

### 2.2.3 Sampling Plans

Implementation of a sound sampling plan and selection of appropriate analytical methods are both essential for site characterization that is adequate for risk assessment purposes. The preceding sections focused on the selection of appropriate analytical methods. This section focuses on the development of an appropriate sampling plan.

Sample collection and analysis may be done at a site for a number of reasons. All of these objectives should be explicitly considered in the sampling plan and discussed in the site investigation report. Often, the data needs of the risk assessment are overlooked in the early stages of the site investigation process. As a consequence, site sampling efforts often do not produce the data necessary to characterize exposures at a disposal site. The sampling plan should ensure the collection of data which can adequately characterize exposures at the disposal site. To that end, potential exposure points and the activity patterns of potential receptors at the site in question should be identified when the sampling plan is being developed. If exposure patterns are considered only after sampling has been completed, the data collected may not provide sufficiently accurate exposure point concentration estimates, and further sampling may be needed. Ideally, the risk assessor's involvement in a project should begin with the sampling plan development stage. If not, the risk assessor must retrospectively evaluate the representativeness of the samples for exposure assessment purposes.

#### Composite Samples

As discussed in the chapter on *Exposure Point Concentration Estimation*, composite samples may provide an efficient way of estimating the average concentration of the

subsamples. However, important information about the subsample concentrations is lost. The range of concentrations cannot be determined from a composite sample, because the highest concentration contributed by a subsample is diluted by mixing with samples of lower concentrations. Furthermore, since the highest concentrations are not detected, hot spots or areas of unusually elevated concentrations may not show up in the data. Thus, while compositing may be an efficient way to obtain an average, it generally does not provide complete information on the range and distribution of concentrations within the area sampled.

### **Contaminant Distribution Considerations**

In addition to determining the areal extent of contamination and the range of concentrations present at the site, the distribution of contaminant concentrations must also be assessed. The sampling plan should be developed in a way that takes into account the need for characterizing the distribution of contaminant concentrations.

For evaluating soil exposures, the average concentration within the exposure area is generally used as a surrogate for time weighted average exposure point concentrations (See *Estimating Exposure Point Concentrations*, Section 7.3.4.5). Systematic or random sampling approaches are generally preferable for evaluating the areal distribution of contaminant concentrations. However, for site assessment purposes other than risk assessment, biased sampling is often conducted. If samples are collected so that certain areas are more heavily represented in the sample set, a weighted average can be used. Weighted averages can compensate for unevenly distributed sampling locations when calculating the exposure point concentration. The *Estimating Exposure Point Concentrations* section of this document presents guidance for calculating an area-weighted average in cases where sampling locations are not distributed randomly or evenly throughout an exposure area.

### **Hot Spot Identification**

Hot spots are a special case of non-randomly distributed concentrations. They are relatively small areas with relatively high contaminant concentrations. The MCP (310 CMR 40.0006) defines Hot Spot as follows:

*Hot Spot means a discrete area where the concentrations of oil or hazardous material are substantially higher than those concentrations in the surrounding area. A hot spot shall be identified based on consideration of both the concentrations of a chemical within a contaminated area and the spatial pattern of that contamination. The areal extent and spatial pattern of a hot spot may be determined through the analytical results from multiple samples taken within the area, or the results of limited sampling in combination with other knowledge about the release, such as the presence of*

*discoloration, odors or a defined source area. In all cases, a discrete area where the concentration of oil or hazardous material is greater than one hundred times the concentration in the surrounding area shall be considered a Hot Spot. Discrete areas where the concentration difference is greater than ten but less than one hundred shall be considered a Hot Spot unless:*

*(a) there is no evidence that the discrete area would be associated with greater exposure potential than the surrounding area; and*

*(b) a site-specific evaluation indicates that the area should not be considered a Hot Spot considering the concentration(s), and distribution(s) of oil or hazardous material, background variability, and/or appropriate statistical analyses. In no case shall concentrations of oil or hazardous material equal to or less than an applicable Method 1 standard be considered indicative of a hot spot.*

In other words, a discrete area where the concentration is greater than ten times the concentration in the surrounding area is a hot spot unless both of the above conditions hold true.

The sampling density needed to detect and delineate a hot spot depends mainly upon its size, and will vary from case to case. An elevated concentration at a single sample location does not necessarily constitute a hot spot. However, elevated concentrations in a single sample may be indicative of the presence of a hot spot, and may warrant further sampling in that area. In deciding whether an exceptionally high result should trigger additional sampling, the investigator should consider: (1) the density of the existing sampling locations; (2) the magnitude of the spike relative to the concentration variability in the nearby samples; and (3) site history.

As discussed in the *Estimating Exposure Point Concentrations* section, hot spots should be evaluated as additional, individual exposure points. The potential for hot spots to exist on the site should be considered in planning the sampling locations and sampling density.

#### **2.2.4 Characterizing Future Environmental Conditions**

If changes in contaminant distribution are anticipated based on fate and transport evaluations, the extent of contamination under future environmental conditions may have to be evaluated in addition to present conditions. Future concentrations cannot be measured and must be modeled. Modeling will be discussed in somewhat greater detail in the chapter on *Exposure Point Concentration Estimation*.

Although biodegradation may be an important attenuation mechanism at some sites, predicting degradation rates that will actually occur in the field at a specific site is

difficult. The application of degradation rates observed under controlled laboratory conditions to field conditions can lead to significant underestimation of future concentrations. The assumption that the concentrations will be decreased at a certain rate by biodegradation is discouraged for risk assessment purposes.

### 2.2.5 Analytical Data Presentation

As specified in 310 CMR 40.0835, the documentation supporting the risk characterization should describe the nature and extent of contamination, including a characterization of sources, nature, and vertical and horizontal extent of contamination at the disposal site; presence and distribution of any non-aqueous phase liquids; tabulation of analytical testing results; and, where appropriate, characterization of background concentrations of oil and/or hazardous materials at the site. Further, the documentation of the risk assessment should contain summary tables which clearly indicate which oil or hazardous materials at or from the disposal site have been identified in each medium at the disposal site and in the surrounding environment. A separate table or set of tables should be presented for each environmental medium. These tables should also present the range of reported concentrations for each OHM detected at the disposal site and in the surrounding environment.

Laboratory data reports should be included in the documentation for the risk assessment. The detection or quantitation limits should be reported as the "Sample quantitation limit", or SQL. The SQL is defined as the method detection limit adjusted to reflect sample-specific action such as dilution or use of a smaller sample aliquot for analysis due to matrix effects or the high concentration of some analytes (EPA 1992). The inclusion of "less than quantitation limit" results in exposure point concentration calculations is discussed in the section on *Estimating Exposure Point Concentrations*.

## 2.3 BACKGROUND

This section of the *Guidance for Disposal Site Risk Characterization* contains a discussion of the term "*background*" and its applications in the characterization of risk at a disposal site. The determination of representative background levels for a disposal site is an explicit requirement of the Massachusetts Contingency Plan (310 CMR 40.0835(4)(f) and 40.0904(2)(b)). This information is used for the determination of the extent of the release of oil or hazardous material, for the risk characterization process itself, and for making clean-up decisions. Despite the numerous important decisions which are based upon knowledge of background conditions for a site, in the past there has been insufficient emphasis on the collection of adequate background samples. The need for identifying background concentrations, including the collection of accurate and reliable data, is reinforced by virtue of the multiple applications of this information. The discussion in this section addresses the regulatory definition of "*background*" and the various uses of background information under the MCP. This section also provides specific guidance on the use of generic background levels published by MADEP, the collection of background data for a variety of media and the comparison of site data sets to "*background*" data sets. Simply put, this section provides the information and guidance needed to answer the following questions:

- *Why is background data important in the MCP and how is it used?*
- *Are the background data collected for the disposal site truly representative of background conditions for the site?*
- *Are the site concentrations reported (for one or more chemicals) consistent with background conditions for the disposal site?*

Ideally, the risk assessor will be involved in the development of the site sampling plan and will have significant input on where and when to collect samples for the site risk characterization. There will, however, be situations where the site data has already been collected, in which case, the risk assessor should review this information (including the background data), discuss its adequacy with the site manager and recommend additional data collection if necessary. The risk assessor must have confidence that the data collected are representative of the site and the site background conditions if this information is to be meaningfully used in the risk characterization process.

It is important to recognize that many anthropogenic chemicals (particularly some chlorinated organic compounds) are expected to have nondetect background concentrations, as these compounds, while common at c.21E disposal sites, are otherwise rare in the environment. Generally speaking, background levels are most important for the various naturally occurring metals found in the environment. It is also quite common to detect "*background*" levels of polycyclic aromatic hydrocarbons (PAH's) in soil, especially in urban areas. Except when MADEP published background levels are used, background should be dealt with on a site-by-site basis and should be medium-specific.

## 2.3.1 The Concept of "Background" in the Massachusetts Contingency Plan

### 2.3.1.1 Definition: 310 CMR 40.0006

In order to discuss the use of background data under the Massachusetts Contingency Plan the regulatory definition of the term is important:

Background means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern which are:

- (a) ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern; and
- (b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, releases to groundwater from a public water supply system, and/or petroleum residues that are incidental to the normal operation of motor vehicles.

The regulatory definition of background makes clear that the term is not limited to "pristine" conditions, and that the Department recognizes that historic human activities have resulted in the presence of some chemicals in the environment. Such non-pristine conditions must meet the conditions described in both of the clauses [(a) and (b)] of the definition, however. It is important to note that, under this definition, oil or hazardous material from one release cannot be considered background for another release<sup>1</sup>.

### 2.3.1.2 Background & Permanent Solutions

Under the MCP, *Permanent Solutions* are implemented to achieve a level of No Significant Risk at a disposal site. The definition of a Permanent Solution is given at 310 CMR 40.0006.

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<sup>1</sup> The January 1995 revisions to the MCP included provisions to address situations in which a property is located downgradient of a property which is the source of the release of oil or hazardous material. The owner or operator of that downgradient property may establish Downgradient Property Status pursuant to 310 CMR 40.0180. These provisions were established in recognition of the fact that, while the upgradient source is not "background" for the downgradient property, the owner/operator of the downgradient property has limited ability to implement a Permanent Solution at that site.

The implementation of a Permanent Solution (or the achievement of a permanent Solution) is the equivalent of conducting a Response Action to achieve a level of No Significant Risk or to control or eliminate sources of oil or hazardous material for a foreseeable period of time. (Note that in the MCP the term Response Action could also include the assessment of a site, but such assessments are not the equivalent of implementing a Permanent Solution.)

#### Definition

Permanent Solution means a measure or combination of measures which will, when implemented, ensure attainment of a level of control of each identified substance of concern at a disposal site or in the surrounding environment such that no substance of concern will present a significant risk of harm to health, safety, public welfare or the environment during any foreseeable period of time.

The regulations also require that, where feasible and to the extent possible, a Permanent Solution reduce the levels of oil or hazardous material in the environment to background (310 CMR 40.0190(5) and 310 CMR 40.1020(1)). This concept of reducing contaminant concentrations as close to background as possible whenever remedial actions are implemented at a site derives directly from the statute (M.G.L. c.21E, §3A(g)) and it is explicitly incorporated in the basic performance standard of the MCP: the *Response Action Performance Standard*, or RAPS (310 CMR 40.0191(1) and (3)(c)).

It is important to understand that the requirement to achieve or approach background levels (where feasible) is separate from the risk-based requirements: if it is feasible to go beyond the minimum requirement of eliminating significant risk, there is a statutory obligation to do so.

The word "*feasible*" is prominent in this MCP requirement, and the criteria to be used in establishing feasibility are described at 310 CMR 40.0860. Note that while these criteria are found in a section of the MCP which describes the requirements for conducting Phase III Comprehensive Response Actions, the evaluation of the feasibility of achieving background is a requirement at all sites where one or more remedial actions (e.g., Release Abatement Measures, or RAMs) are undertaken to achieve a Permanent Solution (310 CMR 40.1020), *even if the Response Action Outcome is achieved before Phase III*. Draft guidance addressing the feasibility issue is under development, with an external review draft expected by July, 1995. Please consult the MCP Hotline for the status of that guidance.

The site background levels become the cleanup goals of the response action if it is feasible to achieve those levels. The proper determination of background levels is necessary both for conducting the feasibility evaluation and for those levels to be used as cleanup criteria.

### 2.3.1.3 Background & Response Action Outcomes (RAOs)

Response Action Outcomes, or RAOs, are the end-points of all response actions conducted under the Massachusetts Contingency Plan, and the documentation that the disposal site has reached an end-point is the Response Action Outcome Statement. RAOs are divided into three main categories (A, B and C) and several subcategories (e.g., A-1, A-2 and A-3) to distinguish between the different types of end-points which may be reached for a given site.

#### Achieving Background Levels Is Considered Feasible unless:

- ▶ The remedial alternative is not technologically feasible (technological feasibility criteria found in 310 CMR 40.0860(5))
- ▶ The costs or risks associated with the remedial alternative would not be justified by the benefits (cost/benefit analysis criteria found in 310 CMR 40.0860(6))
- ▶ Experienced individuals are not available to implement the remedial alternative
- ▶ The alternative would necessitate off-site land disposal and no facility is available
- ▶ The elimination or control of the source of OHM is not achievable by the person conducting the response action

*Summarized from 310 CMR 40.0860(4): consult the regulations for exact wording and more detail.*

When a Permanent Solution has been implemented at a disposal site, a Class A Response Action Outcome applies to the disposal site (310 CMR 40.1035). The subcategories of the Class A RAO are described at 310 CMR 40.1036. As noted in the discussion above, the implementation of a permanent solution must be accompanied by an evaluation of the feasibility of reducing OHM levels to background, and thus all Class A RAO Statements must either document the extent to which site conditions have been reduced to background (for Class A-1 RAOs) or demonstrate that the achievement of background is not feasible (for Class A-2 and A-3 RAOs). This requirement is found at 310 CMR 40.1056(2)(e).

Since Permanent Solutions are not implemented at sites eligible for Class B or Class C Response Action Outcomes, an evaluation of the feasibility of returning the site to background conditions is not required.<sup>2</sup>

<sup>2</sup> Sites eligible for a Class B RAO do not have to implement a Permanent Solution as no remedial actions are necessary to achieve a condition of No Significant Risk. Sites eligible for a Class C RAO have implemented measures to eliminate substantial hazards at the disposal site until such time as a Permanent Solution becomes feasible.

The fact that the background feasibility requirement is only triggered at sites eligible for Class A RAOs is logical in that, if remediation is taking place at a site, the incremental cost of going beyond the risk-based requirement may be small relative to the cost of the remedial action; the remedial workers are already mobilized, plans are already in place for the treatment or removal of remediation wastes, etc.. Thus, in planning the remediation activities consideration should always be given, up front and early in the process, to approaching background conditions. If, on the other hand, no risk-based remediation is necessary and no remedial action plans are developed, the regulations and the statute do not require actions to be taken solely for the purpose of restoring background conditions.

Background & RAO's	
<b>A-1 RAO:</b>	<b>Achieves Background.</b> RAO Statement demonstrates that background cleanup goals are met.
<b>A-2 &amp; A-3 RAO's:</b>	<b>Background levels determined to be infeasible.</b> RAO Statements includes infeasibility demonstration.
<b>Class B &amp; Class C RAO's</b>	<b>Feasibility of Background analysis not required.</b> Permanent Solutions are not implemented at these sites.

#### 2.3.1.4 Background and Activity and Use Limitations (AULs)

Limitations on site use may be part of the package of response actions taken to achieve a level of No Significant Risk at a disposal site. The MCP provides specific tools, called Activity and Use Limitations, described at 310 CMR 40.1012. These limitations and their relationship to the risk characterization process are described in more detail in Section 2.1.3 of this guidance document. There are two points to make concerning the relationship of AULs and background:

- (a) Activity and Use Limitations are not required where the concentrations of oil or hazardous material have been reduced to background (310 CMR 40.0923(3)(b)1 and 40.1012(2)(a)); and
- (b) For the purposes of the requirements of Response Action Outcomes only, Activity and Use Limitations are not considered a "remedial action" (310 CMR 40.1046(3)) and thus the implementation of an AUL does not, in and of itself, trigger the requirement to evaluate the feasibility of reducing concentrations of OHM to background.

### 2.3.1.5 Background in the Risk Characterization Process

The Department focuses assessment and remediation resources on contamination which is attributable to a release of oil or hazardous material and which has the potential to pose significant risk of harm to health, safety, public welfare or the environment. To this end, chemicals which are present at levels consistent with background are removed from the risk characterization process: they are, by definition, at a level of No Significant Risk (310 CMR 40.902(3)). Conversely if a chemical is present at concentrations above background, then it cannot be so eliminated. Thus, background data is one factor used to identify Contaminants of Concern (Section 2.4) for the risk characterization.

Taking this argument further, if all chemicals reported in a given environmental medium (such as groundwater) are present at background levels, then exposure to that medium does not have to be evaluated in the risk characterization. Finally, if *all* chemicals in *all* media at the site are present at background, *or if they have been reduced to background levels through some response action*, then a risk characterization is not required (310 CMR 40.0901(3) and 40.1020(2)) as a level of No Significant Risk is deemed to exist. Therefore reducing contaminant concentrations to background levels can minimize the assessment required at a disposal site, which may potentially lower costs at some sites, particularly for recent, discrete releases.

The risk assessor must determine what contaminants are consistent with background concentrations and document why it is appropriate to drop these contaminants from the process. An accurate determination of background concentrations is essential to enable the risk assessor to make a critical decision as to what compounds will be carried through the risk assessment process. If background has not been adequately characterized the risk assessor might not be able to eliminate from further assessment those chemicals which are consistent with background and ultimately these chemicals will be unnecessarily carried through the risk characterization. In the alternative, chemicals which should be included in the risk assessment might be wrongly dropped out if background concentrations are inappropriately identified. Either result carries with it the potential for additional cost and effort that could be eliminated.

### 2.3.1.6 Background and Technical Justification

The following guidance on gathering and evaluating background data is written to address issues which arise at a wide array of disposal sites, from the simple to the complex. The level of detail of this guidance should not obscure the fact that the scope and level of effort of the risk characterization (including background issues) depend upon the complexity of the disposal site and the response action being performed (310 CMR 40.0903(1)).

At many sites, particularly those resulting from sudden and discrete releases of oil or hazardous material (i.e., "spills"), knowledge about the release and the extent of the response action may be used with only limited analytical information to draw conclusions about background levels. For example, it may be unnecessary to determine background conditions for a fuel oil spill which was quickly contained and completely cleaned up. Knowledge about the quantity of fuel spilled (*is it all accounted for?*), the location of the spill (*was it on pavement or in a well defined area?*) and the nature of the material (*would it have penetrated the soil to great depth? is it soluble in water?*), the nature of the remedial action performed and the results of any confirmatory sampling (*field screening? laboratory analyses?*) could be used to conclude, **based upon professional judgement**, that the spill was remediated to background levels.

Note that such flexibility is inherent in the MCP; the regulations contain language (310 CMR 40.0193) which allows a Licensed Site Professional (LSP) to forgo specific site investigation activities, "*if, in his or her professional judgement any particular requirement is unnecessary or inappropriate based upon the conditions and characteristics of a disposal site.*" The basis of such a technical justification would be described in the pertinent submittal to MADEP. The technical justification should be documented in sufficient detail to enable a reviewer/auditor to evaluate the decision to forego the requirements in question.

### 2.3.2 Identification of Site Background Conditions

As demonstrated above, background conditions should be considered in selecting contaminants of concern, planning remedial response actions, implementing Permanent Solutions, and evaluating the feasibility of reducing concentrations to background. The project manager should consider the importance of the background information when planning the data collection to ensure that adequate resources are devoted to gathering this information. The risk assessor should reinforce the need for obtaining background information and demonstrate how this information can be properly used. The following guidance is provided to assist in the characterization of site background concentrations, including both the use of MADEP published generic background levels and the establishment of site-specific background concentrations.

As will be seen in the sections which follow, it accomplishes little to collect a single sample and declare the chemical concentrations in that sample as "*background*" for the disposal site. Reported concentrations (both background and release-related) may vary over a wide range due to the heterogeneity of the environmental medium, natural variation or the presence of "*hot spots*", or the vagaries of the analytical methods employed. A single sample is no more than a random estimate of what "*typical*" background concentrations might be. Sufficient data is required to provide the site manager and risk assessor a sense of the average or likely concentrations as well as the

variation in levels expected. Ideally, distributions of site-background data should be compared in some fashion to distributions describing the site-release concentrations, although there are circumstances under which a streamlined approach is justified. The important site-decisions made based upon the background data should not be undermined by an inadequate characterization of background. When site-specific background data is sought, it is imperative that a well thought out sampling plan for each medium be developed. When MADEP published lists of generic background levels are used it is important that data be used as described by the Department. The risk assessor must have a high level of confidence that the information collected to establish background is representative of background conditions at that location.

#### **2.3.2.1 MADEP Derived Background Levels**

Historically, MADEP has considered the use of published generic background levels to be an option of last resort, when obtaining site-specific data was not possible. The data which comprise such generic background lists may not be representative of Massachusetts conditions and/or are not comparable to the data obtained at disposal sites. Typically they are collected over a large geographic region, including areas which would not be representative of Massachusetts conditions (e.g., the USGS data (Shacklette, 1984) often submitted to the Department can be narrowed down to data representative of "Eastern U.S. Soils".) Compilations of generic background levels may also include data taken from a number of sources, with internal variation of sample collection, handling and analytical techniques. Thus, the risk assessor should avoid using any list of generic background levels which has not been specifically recommended by the Department.

MADEP recognizes the utility of published background levels, however. The use of published lists of background concentrations can streamline the site assessment and risk assessment process, particularly to provide justification for dropping chemicals from further consideration in the risk assessment. Such values could also be used as target cleanup levels when a Class A-1 RAO is sought, or could serve as the basis for a feasibility analysis submitted as part of a Class A-2 or A-3 RAO. The Department has initiated an on-going project to identify and publish generic background concentrations which would be acceptable for use in c.21E assessments. The first such list, *MADEP Background Soil Concentrations*, is presented below. Additional lists will be made available through the MADEP Bulletin Board as they are developed. Current plans includes the expansion of this list to include polycyclic aromatic hydrocarbons and the publication of a similar list for urban locations.

## MADEP Background Soil Concentrations

Table 2.1 presents the list of Massachusetts Background Soil Concentrations which may be used in lieu of site-specific background levels as part of a c.21E assessment. These values were judged by MADEP staff to be sufficiently representative of Massachusetts non-urban (i.e., suburban and rural) locations that the use of these values at c.21E sites would be protective of public health and the environment.

Table 2.1			
MADEP BACKGROUND SOIL CONCENTRATIONS			
These soil concentrations are derived from a database of background samples taken from rural and suburban locations. The values represent total metal concentrations. These values may be generalized to urban locations pending the publication of a MADEP list of typical urban background levels.			
Chemical	Soil Concentration mg/kg	Chemical	Soil Concentration mg/kg
Aluminum	13,000	Lead	99
Antimony	1.4	Magnesium	4,900
Arsenic	17	Manganese	300
Barium	45	Mercury	0.3
Beryllium	0.4	Nickel	17
Cadmium	2	Selenium	0.5
Chromium	29	Silver	0.6
Cobalt	4.4	Thallium	0.6
Copper	38	Vanadium	29
Iron	17,000	Zinc	116

These concentrations represent the 90<sup>th</sup> percentile values from the collected data set. A high (e.g., 90<sup>th</sup>) percentile was chosen in order to insure that chemicals which are truly present at background levels would be correctly identified as such. By using a high-end background concentration (90<sup>th</sup> percentile) as a point of comparison for all site data, DEP recognizes that some contaminants that are actually elevated may wrongly be treated as background concentrations. The consequences of these errors,

however, will not be serious because the 90<sup>th</sup> percentile levels of the metals listed here are not associated with significant health risks. There may be other substances for which this simplified approach is not appropriate. Table 2.2 presents a more detailed summary of the data used to select the MADEP Background Soil Levels.

It is important to note that a higher (e.g., 95<sup>th</sup>) percentile value was not chosen based upon MADEP staff judgement that the data set used as the basis of this analysis may be biased towards the higher concentrations. The data set was developed from reports submitted to MADEP under the c.21E program. Samples identified in the reports as being representative of "background" at the site under investigation were compiled and analyzed. The data thus collected could have been influenced by some of the following intentional/unintentional biases:

- (a) the samples were taken in the vicinity of disposal sites and may in fact have been affected by the contamination at the sites;
- (b) historically at c.21E sites, background samples are more likely to be taken (and reported to MADEP) in areas with relatively high background levels; samples are less likely to be taken if the concentrations at the site are so low that they are "obviously" background;
- (c) it is possible that some samples taken as background at sites were not included in reports submitted to MADEP;
- (d) high background samples at sites may have been mistaken for contaminated samples and not identified as "background".

The use of these values in a c.21E risk characterization is discussed in Section 2.3.3. These values are intended for use in determining whether levels of metals at **non-urban 21E sites** are consistent with background. They are not necessarily appropriate for use at urban sites or for use in meeting the regulatory requirements of other programs.

### 2.3.2.2 Background Sample Collection and Analysis

Site-specific background determinations are necessary for chemicals not included in the list(s) of generic MADEP Background Concentrations. Site specific background determinations may also be made where it is believed that site-specific background may, in fact, be higher or lower than the published Massachusetts values. For many chemicals, including chlorinated organic compounds, expected background levels would be non-detect, and the risk assessor may adopt a background concentration of zero (or ND) without further analysis.

When site-specific background levels are needed, the collection of adequate data to define background conditions requires consideration of the number of samples to collect, the sample location and the sample collection methodology and timing. When site

concentrations are to be compared to background, a characterization of background conditions is needed for each media sampled as part of the site investigation. Under most circumstances, background is characterized by collecting site-specific environmental samples.

Background sample collection and sample analysis methods should be consistent with those for other site-related samples. For example, if surficial soil samples are being collected in a source area with a hand auger, then the same technique should be used to collect background samples. In addition, background samples should be handled in the same fashion as site samples. For example, if groundwater samples are collected and filtered on-site, the background groundwater samples should be filtered as well. Use of the same sample collection technique and preparation will limit differences in results which are potentially attributable to sample handling. Additional information on sampling methods and analyses is contained in Section 2.2, *Determining the Nature and Extent of Contamination*.

Background and site samples should be collected concurrently whenever possible, to ensure that the analytical results are comparable. This is particularly important for media where concentrations may vary or fluctuate with time, such as groundwater, surface water and indoor or ambient air. By collecting the samples at the same time, you can attempt to control for seasonal variations, changing weather conditions and possible effects associated with the fate and transport of contaminants in the environment.

Timing is less of an issue when the medium and contaminants are more stable in the environment, such as metals in soils at depth, where background concentrations are likely to remain more constant over time. Nevertheless, collecting and analyzing both site and background soil samples at the same time in the same way will reduce the chance of introducing differences in the results that are just artifacts of sampling and analysis procedures and are not actually representative of site conditions.

Collection of both background and site samples should be conducted in accordance with *Environmental Sample Collection and Analyses*, set forth in 310 CMR 40.0017.

Table 2.2

# DETAILS OF THE MADEP BACKGROUND SOIL DATA SET

Chemical	Number of Samples	Range of Values		Mean Values			Percentiles		
		Maximum mg/kg	Minimum mg/kg	Arithmetic mg/kg	Geometric mg/kg		50th mg/kg	90th mg/kg	95th mg/kg
Aluminum	30	24,000	387	8,165	5,536		7,800	13,000	16,000
Antimony	90	22	< 0.002	0.9	0.2		0.34	1.4	4.8
Arsenic	139	99	< 0.1	8.2	4.7		4.8	16.7	24.5
Barium	64	104	0.42	22.2	15		15.7	45.2	52.8
Beryllium	103	1.6	0.03	0.25	0.21		0.23	0.39	0.53
Cadmium	127	5.9	< 0.01	0.8	0.43		0.29	2.06	3.4
Chromium	147	105	0.02	15.2	10.3		10.6	28.6	38.8
Cobalt	10	4.7	< 0.5	1.7	0.8		NC	4.4	4.5
Copper	103	160	< 0.5	16.3	7.7		7.3	37.7	56.1
Iron	30	50,000	444	9,579	6,031		7,200	17,000	22,500
Lead	141	326	1	39.2	19.5		19.1	98.7	158
Magnesium	30	11,000	< 250	2,141	1,028		1,300	4,900	6,700
Manganese	30	460	< 3	140	81.5		110	300	365
Mercury	107	1.4	< 0.0002	0.13	0.043		0.066	0.28	0.43
Nickel	103	48	< 0.5	7.7	4.6		5.1	16.6	22.7
Selenium	93	4.6	< 0.0005	0.32	0.1		0.17	0.5	1
Silver	117	82	< 0.003	0.92	0.09		0.07	0.58	0.91
Thallium	71	5	< 0.005	0.41	0.1		NC	0.6	1.65
Vanadium	30	46.6	< 1	13.6	7.6		10.3	28.5	38.5

## Number of Background Samples

A sufficient number of samples must be taken to allow a meaningful comparison of background concentrations to site concentrations. Generally speaking, **more** background samples are required if:

- there is high variation in the concentration of analytes in the background data set (indicated by a coefficient of variation greater than 50), *or*
- if contamination exists in more than one medium, *or*
- if small differences (small minimum detectable relative difference in inferential statistical tests) between site concentrations and backgrounds may be of concern. When it is acceptable not to detect small differences between background concentrations and site concentrations, fewer samples are required.

When an argument is being presented that remediation of a site is unnecessary because the site concentrations are consistent with background (i.e., when a Class B RAO is sought), or that a permanent solution has been achieved because site concentrations have been reduced to background concentrations, a sufficient number of background samples must be collected to support this assertion. The specific number of samples needed depends in part upon the method used to compare the results.

A number of documents have been prepared by USEPA which describe approaches to determining what is an adequate number of samples. A particularly useful publication is the Guidance for Data Useability in Risk Assessment (USEPA, 1992), hereafter referred to as Guidance for Data Useability. An understanding of basic statistics is helpful in determining background sample size. In the section which follows, entitled **Approaches to Comparisons with Background**, a brief explanation of common statistical terms is provided. It may be helpful however, to refer to a basic statistics text (such as Cochran, 1977; Green, 1979; Snedecor, 1980) for additional information and a more detailed presentation.

The Guidance for Data Useability contains equations (in its Appendix IV) that can be used to calculate the minimum number of samples required to achieve specific statistical goals, such as levels of *power*, *confidence* and *minimum detectable relative difference* (MDRD). It is clear from discussions in environmental statistics texts that the range of chemical concentrations reported is as important as the magnitude of the concentrations when making background-to-site comparisons. The Guidance for Data Useability gives specific examples to demonstrate the influence that variability among samples has on the number of background samples required at a site.

*When considering the number of background samples needed to evaluate variability in the background data, the users of either common sense or statistics will conclude that one or two samples are generally insufficient.*

It is important to remember that not all background samples will need to be analyzed for all analytes. In order to minimize costs and streamline this assessment, those analytes that exhibit a low degree of variability would require fewer background samples to be analyzed. Thus, a cost saving could be obtained if only the analytes with a high degree of variability are analyzed for in every background sample.

### **Selection of Background Sample Locations**

Background samples are collected to assess the levels of contaminants that would exist in the absence of the disposal site of concern, which are ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern, and are attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, or petroleum residues that are incidental to the normal operation of motor vehicles" (310 40.0006). Background samples should be collected in locations that are relatively undisturbed, unstained and unlikely to have been used for handling or storing oil or hazardous materials, or to have been affected by oil or hazardous materials migrating to that location. The sampling location should be based upon similarity of the medium and environmental conditions at the background area and the disposal site's conditions.

The location(s) selected to collect background samples may be either inside or outside of a property boundary. The risk assessor should allow for additional time when scoping this task if access to a property is, or could be, an issue. There may be situations, particularly in some urban and heavily industrial areas, where a suitable location is not available on an adjacent property, and background samples must be collected further from the site. Background samples should not be collected off-site in areas affected by another disposal site.

A review of any existing historical records and the current environmental setting, along with physical observations and field screening data, can be used to select an appropriate location for a site-specific background sample. This type of information should be readily available from the site project manager, as this is basic information for most site investigations.

All available historical records regarding the use of oil and hazardous materials at the disposal site and in the local area should be reviewed. Some typical examples of such records might include, but are not limited to, records available from the

Massachusetts DEP, the United States Environmental Protection Agency (USEPA), the local Board(s) of Health, the local Fire Department(s) and the local Water Department. It is also helpful when possible to obtain historical aerial photographs of the disposal site.

The environmental setting may provide information on where to collect a background sample, such as the upgradient direction for groundwater or the upstream direction of a river. Conversely, the environmental setting may indicate locations where background samples should not be collected, such as a surface area affected by runoff from the disposal site.

In the field, physical observations can often provide a great deal of information. Observations of staining, odors, soil disturbances or stressed vegetation should eliminate an area from consideration as a possible location to collect background samples. Field screening data can also be evaluated to locate a background area. Background samples should not be collected in areas of elevated screening data. In general, optimal locations for collecting background samples are areas where minimal current or past human activity has occurred. For example, in a rural or suburban area, a mature stand of trees may provide an area of relatively undisturbed soil. However, be aware that just because field screening results are negative and the area where the samples were collected appeared undisturbed, one cannot always be absolutely certain that the area actually represents background conditions, and has not been affected by oil or hazardous material. If site-specific background concentrations are high relative to typical background levels, a decision to use those data to make a background determination must be justified by other geological or historical information.

### **Media-Specific Background Considerations**

Many of the factors that are important in determining background conditions are media-specific. A discussion of media specific background considerations is addressed below.

#### **Groundwater**

Background groundwater samples should be collected from an area which is hydraulically upgradient of the disposal site. The background location should be an area which is believed to be unaffected by other releases. The depth of geological strata from which the background samples are collected should be consistent with the sampling depth for the site samples, such that the samples are obtained in the same water-bearing unit. For example, when sampling overburden wells, the background samples should not be collected in the bedrock aquifer. Groundwater flow direction should be considered separately for each water bearing unit when

locating background sampling locations, since the upgradient direction may be different for different units.

The question of whether the groundwater samples in general should be filtered is addressed in the Section on Exposure Point Concentration. The only issue pertaining to filtering background samples is that of consistency. Therefore, whether background groundwater samples from the disposal site should be filtered is dependent upon whether the site groundwater samples were filtered.

## Soil

Background soil samples should be collected from an area where soil conditions are similar to the soil samples collected for the site investigation, excluding the impact of the site in question. Soil can be classified into groups based upon physical characteristics. This classification is routinely conducted by a geologist during field investigations. The physical characteristics most commonly evaluated include grain size, color, moisture content, organic carbon content, gradation and plasticity.

It is important to consider sampling depth when collecting background soil samples. Surficial soil samples are much more likely to be affected by atmospheric conditions and industrial processes than soil samples collected at depth. It may be necessary to collect background samples at various depths at a site to adequately characterize background conditions.

It is useful to take a soil core sample and examine bedding patterns to see if there has been much soil disturbance. This will help determine if composites on selected horizons (e.g. 0 - 5 cm depth) are most appropriate.

## Surface Water

The collection of background samples in a surface water body will vary depending upon the type of water body. In the case of rivers and streams the background samples should be collected from a physically similar location upstream of the site in an area where site contaminants are unlikely to migrate. When a pond or lake is impacted by oil/hazardous materials (OHM), a background sampling location may be available in the same water body at a distant location from the site. If however, the entire pond has been affected it may be necessary to investigate collecting background samples from a similar pond in the same drainage basin. When a "reference pond" is used, special consideration should be given to morphological characteristics such as size, depth, surface water turnover rate and geology, and to lake trophic status as often judged by color, pH, chlorophyll a content, biological standing crop and diversity.

When selecting any surface water location for collecting background samples the surrounding conditions should always be compared to conditions at the site. Some factors to consider include: industrial development in the area, presence of roadways, culverts or run-off areas. The Massachusetts Department of Fisheries, Wildlife and Environmental Law Enforcement maintains historical records of activities of many water bodies in the state which are invaluable

for determining historical impacts to the water bodies. In addition, field screening techniques may be helpful in determining if the background surface water characteristics are similar to the surface water conditions at the site. Some field screening techniques commonly used include pH, conductivity, dissolved oxygen and temperature. Of course, it is important to note that some of these parameters may be altered as a direct result of the OHM from the site, which is why they can be used to indicate non-background conditions. It may also be helpful to collect the background samples at water depths similar to those selected for site sampling.

## **Sediments**

Many of the factors considered in the collection of surface water samples hold true for the collection of background sediment samples. However, in addition to those issues it is also important to consider sediment conditions such as color, organic carbon content, grain size, gradation and redox status. Also, where possible, the current velocity and the depositional conditions should be considered when identifying a background location.

## **Ambient Air**

Background ambient air samples can be collected to analyze for the presence of particulate matter, for specific chemical constituents, or both. Obviously, the choice will be determined by the sampling design used to collect the site samples.

Of primary importance in ambient air sampling is the predominant wind direction for the area. Background samples should be collected in the upwind direction of the site. It is therefore necessary to collect information on predominant wind direction prior to and during the collection of the site and background samples. Locating multiple samplers around the site will improve the chances of collecting adequate background sampling data.

Seasonal variation should also be considered. Both site-related and background air concentrations may fluctuate seasonally, so it is important to collect both types of samples at the same time.

Another important consideration in collecting background data is distance from the site. By collecting background samples at an increased distance from the site the likelihood of interference from the site itself can be decreased. This does have a cost however, since likelihood of having comparable conditions also decreases as you get further away from the site. This may result in increasing the likelihood of impacts from sources that do not impact the site. It is of particular importance that background ambient air samples be collected at the same time as site samples are collected because the potential for mixing and changing conditions is so great. When possible the sampling plan should control for these types of potential confounding variables.

It may be appropriate to collect some preliminary information on the site and the surrounding area prior to actual ambient air sampling, such as identifying other potential sources of air

contamination in the area, determining predominant wind direction and conducting some preliminary field screening.

### Indoor Air

The collection of background samples for indoor air presents some unique and different problems, as compared to the collection of other background media. In each of the previously discussed situations it was recommended that site specific background samples be collected. In the case of indoor air, it may not always be best to base background air concentrations on site specific samples. There are numerous factors which can result in differences between site indoor samples and background indoor air samples. A primary issue is locating an appropriate background sampling location. It is generally not appropriate to utilize an upper level of a structure to collect background samples, because lower concentrations of the same contaminants elsewhere in the building may just be indicative of lower concentrations of the site contaminants. In lieu of using the same building to collect indoor air samples, background samples could be collected in a similar structure. However, regardless of how similar the structures are there are a number of factors that can lead to erroneous background samples, such as:

- differences in building construction and design;
- differences in building age and tightness;
- differences in building construction materials;
- differences in building ventilation;
- differences in volatile compounds present in the structures, unrelated to the disposal site of concern;
- different effects from outdoor ambient air conditions; and
- different depths to the groundwater table.

In general, when sampling indoor air, the sampling plan should include an outdoor sample to determine if the chemicals are unique to the indoor air.

In some cases, it may be more appropriate to use literature values to establish background levels for indoor air. There are recent publications available which may be referenced, including Shah and Singh (1988) and Stolwijk (1990).

The use of published values from the literature may present equally problematic conditions. Shah, for example, compiled indoor air data which had been previously collected. The studies that contributed data were originally done for a variety of purposes. The environment sampled might be either a residential setting or a workplace environment. Moreover, differences exist between the sampling techniques utilized, the duration of the sample collection and the analytical methods employed. The risk assessor should determine the suitability of using any published data set and recognize that limitations exist for this approach to background as well. These limitations should always be discussed in the text of the report.

Table 2.3 provides a summary of medium-specific information which should be considered when selecting background sample locations.

Table 2.3

CONSIDERATIONS IN THE SELECTION OF BACKGROUND SAMPLE LOCATIONS		
MEDIUM	BACKGROUND SAMPLE CONSIDERATIONS	
General	<ul style="list-style-type: none"> <li>• records review</li> <li>• OHMs at site</li> </ul>	<ul style="list-style-type: none"> <li>• visual observations</li> <li>• field screening</li> </ul>
Soil	<ul style="list-style-type: none"> <li>• geologic unit</li> <li>• use and extent of fill</li> </ul>	<ul style="list-style-type: none"> <li>• sample collection depth</li> <li>• soil characteristics</li> </ul>
Groundwater	<ul style="list-style-type: none"> <li>• flow direction</li> <li>• seasonal fluctuations</li> </ul>	<ul style="list-style-type: none"> <li>• different water bearing units</li> </ul>
Surface Water	<ul style="list-style-type: none"> <li>• seasonal fluctuations</li> <li>• flow direction</li> <li>• water quality characteristics</li> </ul>	<ul style="list-style-type: none"> <li>• morphological characteristics</li> <li>• sampling depth in the water column</li> </ul>
Sediments	<ul style="list-style-type: none"> <li>• deposition</li> <li>• surface water flow direction</li> </ul>	<ul style="list-style-type: none"> <li>• sediment characteristics</li> <li>• seasonal fluctuations</li> </ul>
Ambient Air	<ul style="list-style-type: none"> <li>• predominant wind direction</li> </ul>	<ul style="list-style-type: none"> <li>• seasonal fluctuation</li> <li>• distance from site</li> </ul>
Indoor Air	<ul style="list-style-type: none"> <li>• building construction</li> <li>• construction materials</li> </ul>	<ul style="list-style-type: none"> <li>• depth to groundwater</li> <li>• presence of smokers/indoor storage of sources</li> </ul>

### 2.3.3 Comparing Background Levels to Site Data

As described in Section 2.3.1, many decisions made during the assessment and remediation of c.21E disposal sites depend upon a comparison of site conditions to background concentrations. Determination of whether site conditions are consistent with background can be reliably made with appropriate statistical techniques.

*It should be assumed that a detected chemical is present above background concentrations unless it can be otherwise demonstrated.*

### 2.3.3.1 Comparison of Site Data to MADEP Published Background Levels

The Department has established generic background soil levels at non-urban sites for twenty metals, as described in Section 2.3.2.1, and may publish additional values in the future. When comparing these generic background levels to site data, the risk assessor may conclude that the concentrations of an oil or hazardous material is consistent with background conditions if all the site data are equal to or less than the MADEP Background Level for that chemical.

#### **All Site Data $\leq$ MADEP Background Level**

If the analytical results from **one or more** site samples are greater than the established MADEP Background Level, then the risk assessor may either: (a) collect site-specific background data in an attempt to establish that the site data is, in fact, consistent with background conditions, *or* (b) conclude that the chemical is present at levels greater than background concentrations and proceed with the site risk characterization. However, **in any case where site concentrations are substantially higher than the MADEP background levels, the risk assessor will bear a relatively heavy burden of proof in using site specific data to demonstrate consistency with background, and the site specific evaluation will be closely scrutinized in any DEP review.**

### 2.3.3.2 Comparison of Site-Specific Background Levels to Site Data

The sampling design and number of samples necessary to compare the site contaminants to background chemical levels are determined by the distribution of contaminants, the analytical variability, the statistical methodology used for the comparison, and the variation in contaminant levels at the study and background sites (as described in Section 2.2). In order to eliminate or minimize bias from the site-to-background comparison a valid sampling design and appropriate test statistic should be used. It is advisable (and cost effective) to consult with a statistician *before* sampling to determine the sampling design, number of samples, and the appropriate statistical test for your particular situation. While the specific statistical method needed to compare site to background contamination levels will vary according to each evaluation, an outline of what is expected in the comparison of site-to-background contaminant levels and a discussion of the critical factors which must be considered are provided in this section.

#### **Summary Statistics**

Summary, or descriptive statistics for both site and the background samples should be provided in a table in the risk assessment report. (The data used to calculate the statistics should be clearly referenced and available. These are typically found in appendices to the actual site or risk assessment.) The table should provide the

descriptive statistics for the site and background levels of each contaminant, including the *number of observations, the median, minimum, maximum, mean, standard deviation, and geometric mean* (see glossary of statistical terms, Table 2.4). It is useful to include in this table the frequency and limits of detection as well.

Table 2.4

**Statistical Measures Used In Comparing Data Sets**

***Measures of Central Tendency for the Data Set***

Mean:	the arithmetic average, calculated by summing the values and dividing by the total sample size
Geometric Mean:	the antilog of the arithmetic mean of a log-transformed data set
Median:	the 50th percentile value; half the values in the data set are above the median and half the values are below
Mode:	the value that occurs most often in the data set

***Measures of Variability or Spread in the Data Set***

Range:	a single value which represents the difference between the largest value in the distribution and the smallest value
Extremes:	the 2 ends or limits of a data set; the lowest and highest values
Percentile:	the percent of individual values below a particular value
Variance:	a measure of variation among individual values; it is calculated as the average squared deviation from the mean
Standard Deviation:	the square root of the variance
Standard Error:	the uncertainty or variability around a mean or the standard deviation around the mean
Coefficient of Variation:	the standard deviation expressed as a percent of the mean; $SD/mean \times 100 = CV$

The median and mean (arithmetic and geometric) indicate the middle or central level of the contaminant, and allow for a comparison of the difference in the central value between site and background. The range (minimum to maximum) and standard deviation measure the spread and variability in the contaminant levels among the samples, and aid in the assessment of the differences in central values between the site and background. Three to five background samples may be sufficient in some cases to calculate these summary statistics, but more are recommended to make final judgements if the conclusions are ambiguous.

Descriptive statistics may be used to compare the background data set with the samples from the disposal site. This method of assessment should be conducted when the number of background samples is insufficient to achieve the specified power for an inferential procedure (see discussion below).

*Note: In ORS' experience, the use of professional judgement by the risk assessor considering all relevant site information (including historical use of the site, etc...) and simple summary statistics is less likely to lead to erroneous conclusions than the use of a formal inferential statistical test with small data sets. For example when site conditions are truly above background, the risk assessor is less likely (than a statistical test with insufficient power) to erroneously conclude that the site conditions are consistent with background.*

Generally speaking, the data sets should be comparable in size to provide meaningful comparisons. *[This should not, however, be interpreted to mean that the number of site samples must be limited to the number of background samples taken...]* When making comparisons based upon professional judgement, the risk assessor cannot rely upon objective statistical measures (such as power and confidence) to validate the conclusions. Therefore, it is important that the thought process employed is described and well documented so that the reader may evaluate whether the conclusions are proper. (In other words, when exercising professional judgement, the professional should document how and why those judgements were made.)

**When comparing summary statistics, a measure of central tendency and a measure of spread should be compared and interpreted. MADEP recommends comparing the *median* and *maximum* values of each data set to evaluate whether the site concentrations are consistent with background levels. For values that are lognormally distributed, the median is considered the appropriate measure of central tendency to use when comparing distributions, because it is better than the arithmetic mean for representing the location of the lognormal distribution, and it is less heavily influenced by the skewed values in the data set.**

Since these comparisons are typically one-sided, meaning that, from a regulatory perspective MADEP is concerned only if the site concentrations are above background levels, the high end of the observed concentration range (i.e., the maximum value) is recommended as an indicator of the spread in the data.

- If this pair of summary statistics (the median and the maximum values) for the site data set are greater than the corresponding values from the background data

set, then it should be concluded that the site data are not consistent with background.

- Conversely, if both values of this pair for the site data are equal to or less than the background values, then it may be concluded that the site data are consistent with background.

This analysis becomes problematic when the comparison of the median values yields the opposite result from the comparison of the maximum values. For such cases, and only for such cases, MADEP recommends a tolerance limit of 50%:

- If the median value of the site data is less than or equal to the median value of the background data, and the maximum value of the site data is no more than 50% greater than the maximum value for the background data, then it may be concluded that the site data is consistent with background.
- Conversely, if the maximum value of the site data is less than or equal to the maximum value of the background data, and the median value of the site data is no more than 50% greater than the median value for the background data, then it may be concluded that the site data is consistent with background.

Thus, slight differences in a measure may not result in a conclusion that a chemical is a contaminant of concern. This tolerance factor is not intended to imply that slight exceedances of background levels are acceptable, but that, given the sampling uncertainty which exists, such results may be indistinguishable from background levels. Remember that if the site median and maximum values both exceed the corresponding background levels (regardless of the magnitude of the differences), then that is sufficient evidence in this simple approach to conclude that the site data is greater than background levels.<sup>3</sup>

The option of summary statistic comparisons has been included for cases when the background and/or site data sets are not large enough for an acceptable inferential statistical test. Nevertheless, adequate sample sizes are needed to make reasonable decisions. The number of samples that is sufficient depends on a variety of factors, including site geology, the mixture of contaminants present, and the variability in the concentrations of the contaminants of potential concern. It is not possible to specify the optimal sample size a priori. However, these "rules of thumb" are offered to provide

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<sup>3</sup> This approach is recommended because it is simple to implement. It does not have a statistical basis, in that the data distributions are not accounted for in a quantitative manner. Nevertheless, applying this simple rule is unlikely to lead to significant risk assessment/risk management errors. True background concentrations are expected to exceed the MADEP derived values by 50% or more only in exceptional cases.

rough indication of what DEP is likely to consider adequate. In order to assess both the central tendency and the variability of the background concentrations at a location, a minimum of three (3) must be

**If the risk assessor or site manager believes that an incorrect conclusion is drawn due to statistical uncertainty, the option is always available to reduce that uncertainty through the collection of additional background samples and/or performing an inferential statistical test as discussed in the next section.**

taken for each contaminated medium. This value is considered a bare minimum for a small, simple release at a small (< 3 acres) site. For a slightly larger (less than five acres) but still simple site (in terms of geology and number and distribution of chemicals) where the nature of the contamination is not complex, five (5) samples is considered the minimum. For larger, more complex sites, more background samples would be more likely to provide a defensible result.

*Statistical uncertainty due to inadequate sample size can never be used to justify a conclusion that the site conditions are consistent with background.*

It is also useful to graphically depict the site and background data sets, using the data points, histograms or box plots, to support this comparison.

Summary statistics can provide a fair assessment of site contamination, but a statistical test utilizing a sample size large enough to provide appropriate power to detect reasonable difference in the data is necessary to demonstrate that site concentrations are truly consistent with background levels.

### **Inferential Statistics**

The "gold standard" for comparisons of site and background data is the use of a statistical test. Statistical tests utilizing a sample size large enough to provide appropriate power, confidence and minimal detectable relative difference provide conclusive determinations about the relationship between site concentrations and background levels. A statistical test of the hypothesis that the contaminant levels at the site do not significantly differ from the background levels, if done properly, is the most conclusive evidence of that chemical concentrations at the site are consistent with background levels.

*An inappropriate statistical test (too small a sample size producing too low of a confidence level and/or too little power) is insufficient to demonstrate that site concentrations are consistent with background levels. Inappropriate statistical methods and/or insufficient sample sizes are no better than simple assessment of summary statistics, and may even lead to a false conclusion that would not be drawn from the summary statistics.*

While cost is a consideration when using the proper sample size and design to evaluate contaminant levels at a site relative to background, it may prove cost effective to spend more money in the preliminary assessment, rather than investing in an inappropriate solution based on incomplete information and then having to redo the project after further analysis reveals flaws in the original site assessment.

There are numerous statistical methods that could be used for comparing site and background contamination levels. These methods can be generally divided into two categories (parametric and nonparametric), and selection of the appropriate method depends on the distribution of the contaminant data. Nonparametric tests have more relaxed assumptions than parametric tests but they tend to be less sensitive to differences between data sets than parametric tests. For this reason, parametric tests, when applicable, are preferred for comparing site and background data. Nonparametric tests such as the Wilcoxon Rank Sum Test or the Kruskal-Wallis Test can be used effectively, however, and may be appropriate in some cases for comparisons of site data to background levels. Risk assessors are referred to published texts on nonparametric statistics, such as Conover (1971) or Hollander (1973).

One of the assumptions of many parametric tests is that the data are normally distributed. There are several tests (for example: Shapiro and Wilk, 1965; Royston, 1982) to assess whether data are normally distributed, all of which need ten samples or more to have much validity. If the data are not normally distributed, there are a number of transformations which could be used to achieve normally distributed data. The log transformation is commonly used, and is often appropriate for contaminant data. If the contaminant data are normally distributed and if the other assumptions of the parametric statistics are met, then parametric statistical comparisons are more sensitive to differences in contaminant levels between locations than nonparametric tests. Snedecor (1980) provides clear summaries of parametric tests (such as the t-test and ANOVA test) and compares them to some nonparametric tests.

When a parametric test is based on a comparison of the means of two distributions, the means must represent members of normal distributions. The underlying concentration distribution (of individual data points) need not be normally distributed. Therefore, for parametric tests that compare means, it may not always be necessary to transform lognormally distributed data before employing the statistical test.

The risk assessor or statistician conducting the analysis must determine whether to apply a statistical test to the available data, to identify the most appropriate and sensitive test, and to assure that the underlying requirements and assumptions of the test are met. The data sets encountered in environmental sampling at disposal sites are never ideal, because the sample sizes are always small for statistical purposes and the distributions of values are never perfect normal or lognormal distributions. Therefore, an extensive understanding of the principles and practice of statistics is needed to apply inferential techniques appropriately.

Every report using a statistical test for site contamination should contain a discussion of the power, confidence level, and the minimum detectable relative difference between the site and background contaminant levels. These should be considered before sampling a site, because they are the criteria, along with a measure of the variability in contaminant levels, that the risk assessor (or a statistician) needs to determine the requisite number of samples for the analysis. They also inform the site manager or reviewer about the validity of the conclusions, or the likelihood of drawing erroneous conclusions from the analysis of site data.

Assuming that the null hypothesis is defined by the statement "*There is no difference in contaminant levels between the site and background*", the three performance criteria of interest; **power**, **confidence** and **Minimum Detectable Relative Difference** are described in Figure 2.1. (If the null hypothesis is reversed, "*There is a real difference between the site and background data*", then the discussion of power which follows would be applicable to the confidence level, and vice versa.)

The ideal analysis of background and site data provide close to 100% power at a very high confidence level (also near 100%). Such ideal conditions are unlikely to occur at c.21E sites, however, so the risk assessor must consider which factors are most important so that the analysis will result in credible conclusions. From a regulatory viewpoint, the power of the analysis is of primary importance. The power of inferential techniques applied to data at typical hazardous waste sites is expected to range from 50% to over 90%. If the power of a test is lower than 60%, the results should not be considered conclusive, and should not be taken as evidence that site concentrations are consistent with background levels. For non-urban sites where concentrations substantially exceed DEP published background levels, the risk assessor bears a heavier burden of proof, and the power of the test should be greater than 90% to justify a conclusion that site

Figure 2-1

concentrations are attributable to background. Sites where there is geological or historical information that explains the higher levels are considered exceptions to this rule.

**Power ( $1-\beta$ )** should be as high as possible so that the analysis correctly identifies site conditions which are greater than background levels. At a minimum, power should be as high as necessary to draw a conclusion.

Low statistical power could result in the erroneous conclusion that a truly contaminated site poses no significant risk of harm because it was consistent with background conditions when, in fact, a risk assessment should be conducted to evaluate potential risks. Analyses performed with low statistical power could therefore inadvertently jeopardize public health.

The confidence level is of lesser importance in this specific statistical application as Type I errors would result in chemicals present at background levels being evaluated in the risk assessment. Such an error would not pose a risk to health or the environment.

### Important Parameters for Statistical Comparisons

*Examples assume the null hypothesis being tested is:  
"There is no difference in contaminant levels between the site and background."*

**Confidence Level:** The confidence level is  $1 - \alpha$  (times 100 for a percentage), where  $\alpha$  (alpha) is the (one-sided) probability of concluding that the site chemical concentrations are greater than background when, in fact, the site concentrations are consistent with reported background levels. Alpha is also known as Type I error, or the probability of rejecting the null hypothesis when it is true (i.e., a false positive). The confidence level is the probability of correctly concluding that the site concentrations are consistent with background, and this level should be as close to 1 (or 100%) as possible.

**Power:** Power is  $1 - \beta$  (times 100 for a percentage), where  $\beta$  (beta) is the probability of concluding that the site concentrations are consistent with background when, in fact, the site concentrations are greater than background. Beta is also known as the Type II error, or the probability of accepting the null hypothesis when it is false (i.e., a false negative). Power ( $1-\beta$ ) is the probability of rejecting the null hypothesis when it is false, or the probability of correctly concluding that the site concentrations are greater than background levels. Power should be as close to 1 (or 100%) as possible.

**MDRD:** The minimum detectable relative difference is the percent difference required between the site and background contaminant levels.

**Sample Size:** The number of samples in a data set.

Power is not an independent variable, however. The power of a statistical test depends upon three related factors:

(1) the acceptable  $\alpha$ , or Type I error. The power of a test can be increased if  $\alpha$  is increased (i.e., if the confidence level is decreased). In the extreme, however, reducing the confidence level in order to increase the power of the analysis defeats the purpose of this assessment as it would be rare to conclude that a chemical is present at levels consistent with background. Type I error should not be greater than 0.5.

(2) the minimum detectable relative difference (MDRD). Since it is easier to detect larger differences in data sets than it is to detect slight differences, the power of a test can be increased by increasing the MDRD. In specifying the MDRD, the statistician (or risk assessor) is specifying how far above background the chemical concentration would have to be before it is considered important. An analysis using an extremely high MDRD would be meaningless, however, as the increased statistical power would be gained at the cost of missing sites with potentially significant contamination. The Minimum Detectable Relative Difference (MDRD) achieved should be no greater than 50% of the median value of the background data set (in a test of log-transformed data sets the MDRD should translate into an increment no greater than 50% of the median value of the untransformed background data set.)

Table 2.5

Types of Erroneous Conclusions When Comparing Site and Background Data Using Inferential Statistics		
Assumes the null hypothesis ( $H_0$ ) being tested is: "There is no difference in chemical concentrations between site and background."		
Conclusion from statistical analysis	Actual Condition	
	Chemical concentration greater than background ( $H_0$ is false)	Chemical present at background concentrations ( $H_0$ is true)
Chemical concentration is greater than background (Reject $H_0$ )	<u>correct conclusion</u> $1 - \beta$	<u>incorrect conclusion</u> Type I error $\alpha$
Chemical present at background concentrations (Accept $H_0$ )	<u>incorrect conclusion</u> Type II error $\beta$	<u>correct conclusion</u> $1 - \alpha$
(Table modified from Glantz, 1981)		

- (3) the number of site and background samples which have been taken. The simplest way to increase the power of a statistical test is to increase the number of background and/or site samples. The number of site and background samples should be approximately the same to maximize the power for a given total number of samples. Note that increasing the number of samples will also increase the confidence level of the test as well.

*The risk characterization report should include the calculations of power and confidence for the statistical test conducted, and a discussion of the implications of the results of those calculations. The Minimum Detectable Relative difference should be identified, and that value should be small enough to be sure that sites with contamination above background levels will likely be identified.*

The risk assessor should explicitly consider these factors when discussing data needs with the site manager (i.e., when determining the necessary number of site and background samples). The EPA's Guidance for Data Useability discusses in detail the relationships between alpha, beta, minimum difference, data set variance and how to estimate sample size.

## 2.4 CONTAMINANTS OF CONCERN

All chemicals detected at the site should be considered contaminants of concern and should be carried through the risk assessment process, unless there is a specific, justifiable rationale for dropping the contaminant from the quantitative risk characterization. The selection of contaminants of concern should be evaluated in light of the specific conditions associated with each individual disposal site. The risk assessment report should document the process of identifying the contaminants of concern, and it should list the chemicals that are identified for both the human health risk assessment and the ecological risk assessment. The specific basis for eliminating a chemical detected at the site from the list of contaminants of concern should be clearly delineated in the text of the report.

All oil and hazardous material detected at a site should be included in the risk assessment unless one of the following conditions is true:

- The chemicals are present at a low frequency of detection and in low concentrations; or
- The chemicals are present at levels which are consistent with "background" concentrations for the area and there is no evidence that their presence is related to activities at the site; or
- The chemicals are field or laboratory contaminants.

Each of these rationales will be discussed individually.

**NOTE:** It is important to recognize that the term "contaminant of concern" is not synonymous with the term "indicator chemical". The latter term, was previously used by the EPA when a particular chemical was used as an indication of the presence of or risk posed by other contaminants at the site. The EPA no longer advocates the use of indicator chemicals because the practice may not accurately reflect the total site risk and in general may detract from the accuracy of the risk assessment. The EPA now recommends the use of chemicals of potential concern [*Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual, Interim Final, December 1989*].

### 2.4.1 The Role of the Risk Assessor

The data collected at the site must be reviewed by the risk assessor. Once the analytical data are determined to be sufficient for risk assessment purposes, the contaminants of concern can be identified. As a general rule, the sampling data is likely to be sufficient if the samples are sufficiently representative of the exposure area; the data quality conforms with the guidance in Section 2.2: the samples have been collected and handled

in accordance with standard procedures for the collection methodology; and the samples were analyzed at a certified laboratory in accordance with appropriate laboratory methodologies and established protocols, including the criteria for environmental sample collection and analyses set forth in 310 CMR 40.0017.

#### **2.4.2 Very Low Frequency of Detection and Concentration**

Substances detected at very low frequencies *and* concentrations may be omitted from the risk assessment process. The purpose of this criterion is to eliminate from a risk assessment any substance that is not present consistently enough or at high enough concentrations to contribute to exposure.

##### **Low Concentrations**

The term "very low concentration" refers to the concentration of the chemical relative to the method detection limit. For the chemical to be identified as a contaminant of concern it must be present in a concentration above the detection limit. As the chemical concentration approaches the method detection limit however, the level of confidence in accurate quantitation decreases. The method detection limit (MDL) is the smallest concentration of a chemical which can be accurately measured considering the instrumentation and background noise. The EPA defines the MDL as three times the standard deviation of seven replicate spiked samples run according to the complete method. A further discussion of detection limits is included in the section of the guidance entitled *Extent of Contamination*.

For use in the risk characterization process, the *EPA Guidance for Data Useability in Risk Assessment* recommends the use of sample quantitation limit (SQL), which is the MDL adjusted to reflect sample-specific action, or the MDL itself. In general, the risk assessor should evaluate the type of detection limit identified in the site data as a part of an evaluation of the overall quality of the data. Instrument detection limits should never be considered appropriate for use in the risk assessment. Use of the MDL is appropriate and use of method reporting limit or the practical quantitation limit (PQL), the MDL multiplied by a factor of 2 to 5, may be appropriate. The use of the PQL is generally acceptable, unless the PQL is unusually high. The risk assessor should consider the site specific conditions in deciding if the use of the PQL is appropriate.

The risk assessor may have to decide whether or not to use qualified data in the risk assessment. The data may be qualified due to concerns regarding chemical identification, chemical concentration, or both. One of the most commonly encountered types of data qualifiers are "J" values, utilized in the EPA Contract Laboratory Program (CLP). The use of a J value may indicate that the identification of the contaminant is uncertain or approximate or that the concentration of the contaminant in the sample is uncertain or

approximate. The *USEPA Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual, Interim Final, December 1989 (RAGS)* recommends the use of J-qualified concentrations, but cautions that care should be exercised if the risk is being driven by the qualified data results.

When the risk assessor has determined that the detection limit presented is appropriate and the concentration of the analyte is very close to that detection limit, the next step is to determine the frequency of detection of the analyte at the site.

### **Very Low Frequency**

The frequency of detection will be evaluated at each disposal site based upon the total number of samples collected, the sampling design and the total area sampled. In order to establish that the frequency of detection is very low, the risk assessor should first determine that the total number of samples collected was adequate to characterize the extent of contamination at the site.

There is no established number for what constitutes very low frequency of detection, but in general this number should be limited to one or two samples. This number will be a function of total sample size and as such it would not be appropriate to consider contaminants detected in one to two samples as very low frequency when the total sample size was only five or six samples. Generally speaking, unless there are at least ten samples, very low frequency ought not even be discussed.

It is also critical when considering total sample size that the samples included in the total were collected in the same medium and that, within that medium, the conditions are similar. For example, to determine that the frequency of detection of a contaminant is very low in soil samples collected at the site, the risk assessor should compare these samples to other soil samples collected at comparable depths in an area where the soil has similar characteristics (grain size, etc).

When determining whether the frequency of detection of a particular contaminant is very low at the site, it is also important to consider the spatial relationship of that sample relative to other samples at the site. For example, a contaminant may only be detected in 2 out of 20 total samples, but those two samples might be located in a particular portion of the site and may represent a localized area of contamination. The MCP 40.0924 (2) requires that localized "hot spot" areas be dealt with as distinct exposure points. A hot spot is defined in the MCP at 310 CMR 40.0006 and is discussed in greater detail in Section 2.2 of this guidance.

Finally, a chemical should not be ruled out as a contaminant of concern, even if the levels are detected in very low concentrations and very low frequency, when there is historical

or present use of the chemical at the disposal site. In this situation, it is not possible to definitively conclude that a chemical detected in only a small number of samples is not associated with use of that chemical at the site; therefore it should be carried through the risk assessment.

### 2.4.3 Background

Once the presence of oil and/or hazardous materials has been documented at a disposal site, the risk assessor must evaluate the list of chemicals in relation to background conditions.

*Background* is defined in the Massachusetts Contingency Plan (MCP) 310 CMR 40.0006 as:

Those levels of oil and hazardous materials that would exist in the absence of the disposal site of concern which are:

- (a) ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern; and
- (b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, and/or petroleum residues that are incident to the normal operation of motor vehicles.

When chemicals are present at levels which are consistent with background and there is no evidence that the presence of that chemical is related to disposal at the site, then those chemicals need not be carried through the quantitative risk assessment process. The guidance addresses the determination of consistency with background in much greater detail in Section 2.3 on *Background*.

### 2.4.4 Field or Laboratory Contaminants

Contamination may be introduced into a sample during sample collection, transport or laboratory handling and analysis. A variety of quality control samples such as equipment blanks, trip blanks and method blanks should be collected and analyzed to determine whether contaminants are being introduced by field or laboratory practices rather than as a result of the release. A careful review of quality assurance and quality control data should be conducted as part of an investigation to avoid including chemicals attributable to sampling or laboratory activities in the assessment, while ensuring that chemicals which are site-related are not eliminated from further evaluation. When assessing the potential for field or laboratory contamination the risk assessor should consider:

- the concentrations of chemicals detected in both the environmental and the blank samples;
- the types of contaminants detected in the samples, with particular attention to chemicals commonly used in a laboratory ; and
- historical information regarding chemical use at the site.

The Office of Research and Standards (ORS) recommends that when the concentrations detected in the site samples are higher than the concentrations detected in the quality control samples, the chemicals should either be considered contaminants of concern, or new samples should be collected. In the alternative, when the concentrations detected in the quality control blank samples are comparable to the concentrations detected in the site samples, those contaminants may be eliminated from a quantitative risk assessment, unless those contaminants are otherwise associated with the site based upon other evidence, such as a history of prior use of that chemical, or associated chemicals, at the site. In this situation, it may also be prudent to return to the site and collect both the site and the quality control samples again. Although it is acknowledged that this is not always possible, this step will aid in determining the actual source of the contaminant.

Table 2.5 identifies the recommended procedure for dealing with contamination in the blank quality control samples.

Table 2.5

CONTAMINANT CONCENTRATION	RECOMMENDED INITIAL EVALUATION	ALTERNATIVE EVALUATION
Site Sample > Blank	Resample	Include in the Risk Assessment as a Contaminant of concern
Site Sample ≤ Blank	Resample if deemed necessary	Eliminate based upon other evidence, such as site history and the nature of the contaminant

Although the EPA has established guidelines to use when comparing results from analysis of blanks and of environmental samples, **this approach is generally not recommended** for screening out chemicals at 21E sites. EPA guidelines were developed for use at large Superfund sites where the data sets are generally quite large. ORS does not recommend the EPA approach because of the small sample size frequently encountered at 21E disposal sites. If the risk assessor chooses to use the EPA approach, technical justification for this approach should be provided. However, when resampling to confirm the presence or absence of the contaminant is possible, this is often the best

alternative for determining whether the contaminant is present as a result of the release, or if it was introduced during sample collection or handling.

#### 2.4.5 Lead as a Contaminant of Concern

The presence of lead at a site is often problematic because of the way that lead is regulated under MGL c.21E and the MCP. Lead is considered a "*hazardous material*" and as such is regulated under MGL c. 21E. A release or threat of release of lead can result in classification as a site, in accordance with MGL c. 21E Section 2. There is, however, a distinction between the definitions of *site* and *disposal site* under MGL c. 21E, and the distinction is important in that some of the requirements set forth in the MCP apply only to disposal sites and not to all sites. A site is defined as:

*"...any building, structure, installation, equipment, pipe or pipeline, including any pipe into a sewer or publicly-owned treatment works, well, pit, pond, lagoon, impoundment, ditch, landfill, storage container, motor vehicle, rolling stock, or aircraft, or any other place or area where oil or hazardous material has been deposited, stored, disposed of or placed, or otherwise come to be located. The term shall not include any consumer product in consumer use or any vessel." (MGL c. 21E section 2)*

A disposal site is similarly defined, however, there are a few differences that should be noted. A disposal site is defined as:

*"...any structure, well, pit, lagoon, impoundment, ditch, landfill or other place or area, excluding ambient air or surface water, where uncontrolled oil or hazardous material has come to be located as a result of any spilling, leaking, pouring, abandoning, emitting, emptying, discharging, injecting, escaping, leaching, dumping, discarding or otherwise disposing of such oil and/or hazardous materials. The term shall not include any site containing only oil or hazardous materials which are: lead-based paint residues emanating from a point of original application of such paint; resulted from emissions from the exhaust of an engine; are building materials still serving their original intended use of emanating from such use; or resulted from a release of source, byproduct or special nuclear material from a nuclear incident, as those terms are defined in 42 USC Sec. 2014, if such release was subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under 42 USC. Sec. 2210." (MGL c. 21E Section 2, emphasis added)*

As a result of the definitions of site and disposal site, releases of lead in the form of lead-based paint residues and/or from automobile exhaust are exempted from notification under the MCP (310 CMR 40.0317(8)). However, since lead is a hazardous material regulated under the statute, a Response Action may still be required at sites where such material has been released (310 CMR 40.0370).

Thus, when lead contamination is present in an environmental medium, it should be considered a contaminant of concern for the purposes of the risk characterization, regardless of its origin. At sites where no other notification requirement is triggered, however, persons undertaking response actions to address lead from lead-based paint or automobile exhaust would not be subject to the submittal requirements, approvals, or fees specified in the MCP (310 CMR 40.0370(2)).

## **2.4.6 Additional Issues for Consideration**

### **2.4.6.1 Toxicity Screening**

The Department does not recommend the use of toxicity screening to eliminate chemicals prior to the risk assessment at a disposal site. The use of EPA's concentration-toxicity screen, as described in the *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A)*, December 1989 section 5.9.5 is not recommended. The risk assessment process itself considers toxicity in estimating risks; it would be premature to eliminate contaminants before the risk assessment is performed.

ORS does not recommend the practice of screening out contaminants based upon this criteria despite the fact that they are not toxic at low doses and high concentrations are not usually associated with exposures at disposal sites. At some level even essential human nutrients may have adverse effects. If chemicals are eliminated based upon their being classified by the risk assessor as essential human nutrients, the report should contain a thorough discussion of the technical justification for taking such a step. In the alternative, the chemicals should be carried through the risk assessment process.

A contaminant of concern should not be screened out based solely upon human health risk considerations. Some chemicals which might be considered unimportant in the assessment of human health risk may still present a risk to the environment or to public welfare. The potential effects of contamination should be evaluated comprehensively through the quantitative risk characterization process.

The risk assessor may need to generate different lists of Contaminants of Concern to address risks to human health and the environment, and these lists should be clearly identified in each section of the assessment.

### **2.4.6.2 Chemical Species**

When identifying contaminants of concern it may be important to consider specific states of the chemicals. Depending upon the specific state of the chemical that is present at the site, there may be different health or environmental effects associated with the chemical. This phenomenon is commonly encountered with differences in oxidation states of

metals, where changes in oxidation states can result in changes in absorption or toxicity. For example, hexavalent chromium is more toxic than trivalent chromium. In addition, some compounds may degrade over time and products of degradation may have different toxicity parameters than the parent compound. The risk assessor should consider these factors and may want to discuss these issues when identifying the contaminants of concern.

#### 2.4.6.3 Groups of Compounds

When reviewing the analytical data available for the disposal site some of the data may be presented for groups of compounds rather than for each individual component. Data on groups of compounds is not generally useful in the risk assessment process. Toxicity information used to estimate risk is compound specific; therefore, the estimation of risk associated with exposure to compounds that are identified as a group can be highly inaccurate or impossible, and as a result is not generally recommended. The individual chemicals are the Contaminants of Concern, but for simplicity's sake may be described as groups of compounds in discussions within the risk assessment. The Dose Response Section of the guidance addresses this issue in greater detail.

One of the most commonly detected groups of compounds at disposal sites are total petroleum hydrocarbons (TPH). For a further discussion of TPH data at disposal sites see the *Policy for the Investigation, Assessment, and Remediation of Petroleum Releases - Interim Site Investigation Protocol Document, WSC-401-91 (4/91)*, and the *Interim Final Petroleum Policy: Development of Health-Based Alternative to the Total Petroleum Hydrocarbon (TPH) Parameter, June 1994*.

#### 2.4.6.4 Tentatively Identified Compounds

When gas chromatography-mass spectrometry (GC-MS) is used to analyze for the presence of organic compounds, the instrument is calibrated for certain chemical standards. These standards represent the target compounds which are being analyzed in the samples. When compounds are identified in the sample, but the GC-MS instrument was not specifically calibrated for those compounds, they are designated as tentatively identified compounds (TICs). The mass spectrum of the sample is compared to a computerized library of mass spectra, but since there is no standard calibrated for the TIC, the identification is less certain than for target compounds. The *EPA Data Useability Guidance Document* identifies several techniques which can be employed to increase the confidence in identification and quantitation of TICs:

- the TIC data should be reviewed by an analytical chemist trained in the interpretation of mass spectra and chromatograms;

- the identification of the TICs should be checked against the chromatographic retention indices or relative retention times;
- the TICs should be compared to available site information regarding past use of the site and chemicals associated with prior uses of the site;
- the sample could be re-analyzed using a specific standard.

Another advisable step is to evaluate whether the TIC is likely to be associated with other compounds detected at the site. The result may support the tentative identification or may aid in making a decision regarding the need to re-sample.

The risk assessor may be able to classify the TICs as belonging to a particular class of compounds, such as aliphatic hydrocarbons or polycyclic aromatic hydrocarbons, and as such can qualitatively discuss the significance of these TICs. When dealing with the TICs qualitatively the impacts on cumulative site risk and overall uncertainty should be discussed. The data should be reviewed by an experienced analyst to obtain an "order of magnitude" estimate of the concentration, prior to any discussion of qualitative risk posed by the TICs.

The purpose of this discussion is not to encourage the risk assessor to identify more TICs at sites, but rather, to provide guidance on how TICs that are identified can be dealt with at a site. The risk assessor should note when he/she specifically requests the identification of the TICs at the site, as opposed to a situation where the TICs were just identified as a part of the comprehensive site investigation. The risk assessor must use his/her professional judgement in dealing with TICs, especially when the TICs are potentially associated with a significant health risk. The concentrations of TICs v. concentration of identified compounds should be discussed in terms of the overall risk associated with the site.

#### **2.4.6.5 Comparison to Regulatory Standards & Guidelines**

A chemical should not be ruled out as a contaminant of concern because it is below a standard regardless of the risk characterization method used. It is appropriate to compare individual exposure point concentrations to standards when conducting a Method 1 or Method 2 risk assessment, as this is the actual risk characterization process for those methods. However, when conducting a Method 3 risk characterization, screening substances out of the risk assessment because they are below applicable or suitably analogous standards is not appropriate. In Method 3 it is appropriate to compare the exposure point concentrations at the site to applicable or suitably analogous standards, but that is only part of a Method 3 characterization. The contaminants of concern must also be carried through the risk assessment process to comply with the

MCP and determine if a level of no significant risk has been reached. Therefore, even if the contaminant concentration is below the Massachusetts Drinking Water Quality Standards promulgated in 310 CMR 22.00 the chemical should be included as a contaminant of concern and carried through the Method 3 Risk Assessment process.

#### **2.4.6.6 Comparison to Reporting Concentrations**

The Reporting Concentrations (RCs) should only be used to determine whether a release needs to be reported to the Department. It is not appropriate to eliminate chemicals as potential contaminants of concern, based upon the fact that the concentrations are lower than the RC for the particular chemical.

#### **2.4.6.7 Mobility, Persistence, and Bioaccumulation Potential**

When identifying contaminants of concern at a disposal site it is not appropriate to eliminate them from the risk analysis based upon physical or biological properties that suggest reduction of the chemical in the future.

## 2.5 SIGNIFICANT FIGURES

The risk assessor should keep in mind the accuracy and precision of the environmental data, toxicity information and exposure assumptions used in the course of an MCP Risk Characterization. Environmental measures such as Exposure Point Concentrations, calculated Method 2 standards, and estimated cancer and non-cancer risks are continuous variables whose exact values are unknown and unknowable. Such values should be expressed in as many significant figures as is appropriate.

There are conventions for determining the appropriate number of significant figures and how to round the 20-digit value calculated by a spreadsheet to the appropriate number of significant figures.

### 2.5.1 What Is A Significant Figure?

In general, significant figures (digits) in a number include the left-most non-zero digit to the right-most digit written

Thus:     241  
          24.1  
          0.00241, and  
          2.41 E-2

all have three significant figures.

Terminal zeros may be significant or may be used solely to fix the decimal point (the number 240 may have two or three significant digits) and such numbers can be written in scientific notation to explicitly denote the number of significant digits (2.4 E+2 would have two significant digits while 2.40 E+2 would have three).

### 2.5.2 Rounding Off Values to the Appropriate Number of Significant Figures

Rounding off of values to the appropriate number of significant figures should occur as the last step of the calculations, and should not follow each stage of the calculations.

Rounding a number to the appropriate number of significant figures involves dropping one or more digits to the right of the last significant figure. When more than one digit is to be dropped, the rounding off should be done as a block and not one figure at a time:

- When the first digit dropped is less than 5, the last digit retained should remain unchanged.
- When the first digit dropped is greater than 5 then 1 is added to the last digit retained.
- When the first digit dropped is equal to 5, then 1 is added to the last digit retained if that digit is odd.

When adding or subtracting numbers, the answer should contain digits only as far as the first column containing a significant figure:

Examples:

12.5	0.076	20	20.0
14.47	2.35	17.376	17.376
+ 98.3	+ 1.954	+ 5.2	+ 5.2
<hr/>			
125.3	4.38	40	42.6

Note the difference between the last two answers: the value of 20 in column 3 is taken to have 1 significant figure, while the 20.0 in column four has three significant figures. The value of 20 in column three could also read as having two significant figures and knowledge about the source of that number would determine whether one or two digits would be appropriate.

When multiplying or dividing numbers, the answer should be rounded off to contain only as many significant figures as are contained in the least exact factor. For example,  $6.834 \times 7.35 = 50.2$ , since 7.35 has only three significant digits. This is an approximation of a more exact rule that the fractional (or percentage) error of a product or quotient cannot be any less than the fractional or percentage error of any one factor. For this reason, numbers whose first significant figure is 1 (or occasionally 2) must contain an additional significant figure to have a given fractional error in comparison with a number beginning with 8 or 9.

For example,  $9.84 \div 9.3 = 1.06$ . By the simple rule stated above, the answer would be 1.1, but  $1.1 (\pm 0.1)$  has a percent error of approximately 10%, much greater than the percent error contained in the value of 9.3 ( $9.3 \pm 0.1$  has a percent error of approximately 1%).

Analytical results received from a laboratory will be reported in as many significant figures as is justified, given the accuracy and precision of the analysis. For example, the analyses of 3 rounds of groundwater samples could yield the following results for a drinking water supply well:

Benzene . . . . .	29 ppb	(2 significant figures)
Benzene . . . . .	5.5 ppb	(2 significant figure)
Benzene . . . . .	347 ppb	(3 significant figures)

For the purpose of this example, assume that the Exposure Point Concentrations calculated from this data should be the arithmetic mean of the results from the three sampling rounds:

$$\text{EPC} = (29 + 5.5 + 347) \div 3 = 130$$

The value of 130 represents the results of the calculation (127.16667 by hand calculator) rounded to 2 significant figures. Note that the divisor, 3, is an exact number: the number of samples. Mathematical operations involving exact numbers do not reduce the accuracy and precision of the result and thus are not considered in determining the appropriate number of significant figures. (Another way of looking at this is that the value 3, being know exactly, could have been written as 3.000...or 3.0000000000 to denote the accuracy and precision of this value.)

### Example 2.1

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### 3.0 SELECTION OF RISK CHARACTERIZATION METHOD

The Massachusetts Contingency Plan identifies three methods for the characterization of risk at a disposal site. In general, the selection of the method for a given disposal site is based upon the personal choice of the parties conducting the site assessment, in conjunction with the criteria set forth in the MCP at 310 CMR 40.0942. The most straight forward method is Method 1 which uses promulgated standards to characterize the risk posed by the disposal site. Method 2 builds on this approach by continuing to use promulgated standards, but adds some site specific information. Finally, Method 3 characterizes risk through the application of site specific methodologies. There are, however, some limitations on the use of the methods. This section will first discuss the general limitations applicable to all three methods, and then address each of the methods individually.

#### 3.1 GENERAL LIMITATIONS

The method selected for the risk characterization should be clearly identified in the report. The site should be adequately characterized prior to assessing the risk posed by the site. In general, only one method should be used for a specific release, and the Response Action Outcome (RAO) Statement for each release should be based upon the one method selected. Risk Characterizations conducted to support an RAO Statement for a *portion* of a disposal site are discussed in Section 3.5. There are a few particular situations where methods may be combined. These situations will be addressed in each of the specific sections discussed below.

#### 3.2 RESTRICTIONS ON THE USE OF METHOD 1

When determining whether Method 1 can be used to characterize the risk of harm to health, safety, public welfare and the environment, the risk assessor should scrutinize criteria found at 310 CMR 40.0942. It is expected that Method 1 will be an option at the majority of c.21E sites. At certain sites, however, the risk assessor will have to supplement the Method 1 risk characterization with some form of a Method 3 assessment, while at other sites Method 1 will not be an available option. This section describes the circumstances under which Method 1 may or may not be employed. Method 1 is never required for particular sites, however. It is up to the risk assessor to determine the appropriate risk characterization approach from among the methods identified as applicable to the site.

### 3.2.1 When Method 1 Alone May Be Used

Method 1 can be used as the sole form of risk characterization at sites where (a) the contamination is limited to the soil and groundwater, (b) there are no chemicals which bioaccumulate within the top two feet of soil, *and* (c) all the contaminants of concern present have Method 1 standards promulgated by MADEP in the Massachusetts Contingency Plan. It is expected that Method 1 will be an optional risk characterization approach at the majority of simple sites, as soil and groundwater are the environmental media most commonly contaminated and MADEP has developed standards for the most commonly reported chemicals.

### 3.2.2 When Method 1 Can Be Used In Combination With Method 3

For sites which do not meet the criteria for using Method 1 alone (listed above), a number of options are available, including the use of Method 1 in combination with risk characterization Method 3 *under limited circumstances*. (The Method 3 assessment in these mixed-Method cases is focused on the potential ecological risks associated with the site.) The risk assessor may also choose to employ Method 2 and/or Method 3, as described in Section 3.0 of this document and at 310 CMR 40.0942 of the MCP.

The combination Method 1/Method 3 risk characterization is an option at sites where *either* of the following conditions prevail:

- The contamination is not limited to soil or groundwater, but the exposure to humans comes predominantly from those media; or
- Chemicals which bioaccumulate are present in the top two feet of soil at a site which would otherwise meet the requirements for conducting a Method 1 risk characterization.

In the first set of conditions, Method 1 may be used to evaluate the soil and groundwater, and Method 3 would be used to evaluate the risk of harm to public welfare and the environment from the other contaminated media. This combination approach was written into the regulations in order that sites where there is minor sediment or surface water contamination could benefit from using the Method 1 standards while still adequately evaluating the potential environmental risks in a meaningful way (Method 3). Note that the human health risks associated with the sediment or surface water (or other media) must still be addressed to provide adequate demonstration to the Department that the soil and groundwater exposures are "*predominant*". In other words, the human exposures to the other media (not soil or groundwater) must be relatively minor, meaning that the cumulative risks associated with those exposures should be at least an order of magnitude below the MCP cumulative risk limits (i.e., a cumulative excess lifetime cancer

risk no greater than one-in-one million, and a cumulative hazard index no greater than 0.1.) If the risks are greater than those levels, then the site as a whole must be addressed using the cumulative risk approach (Method 3.)

In the second set of circumstances, it is important to note that in developing the Method 1 standards, potential terrestrial ecological impacts were not considered. It is therefore not possible to conclude that a condition of no significant risk of harm to the environment exists when Method 1 is used to characterize risk at sites where contamination in the soil may pose ecological risk. Recognizing this limitation of the Method 1 soil standards, DEP requires additional site-specific ecological risk assessment at those sites most likely to pose a risk to terrestrial receptors. Rather than require ecological risk assessments at all sites with soil contamination, however, the need for additional assessment is triggered by the presence of bioaccumulating chemicals in surficial soil. The use of these two factors (a chemical's presence in surficial soil and that the chemical bioaccumulates) is considered by DEP to be adequate screening criteria for the purpose of streamlining the c.21E risk characterization process. The combination Method 1/Method 3 approach is used at these sites to insure that those potential terrestrial exposures are evaluated using an appropriate approach (a Method 3 environmental risk characterization) while Method 1 is used to otherwise characterize the potential human health risks.

Section 9.0 of this document, which provides guidance for conducting a Method 3 environmental risk characterization, should be consulted whenever a combined Method 1/Method 3 assessment is conducted.

When either of these combined approaches is used to support a Response Action Outcome Statement, both Method 1 and Method 3 should be checked off on the RAO Form (Form BWSC-004).

### **3.2.3 When Method 1 Is Not An Option**

Method 1 is not an option and cannot be used at sites where: (a) the contamination present at the site is located in an environmental medium which is not soil or groundwater (unless human exposures to such contamination is minor as described above), in which case Method 3 is used to characterize potential risks, or (b) there are contaminants of concern present for which MADEP has not developed Method 1 standards, in which case either Method 2 or Method 3 may be used to characterize potential risks.

## EXAMPLE

*An underground storage tank has leaked heating fuel under a residential structure. The tank was removed, but residual contamination exists under the building. No soil gas studies were conducted and no indoor air sampling was done. Is it appropriate to use Method 1 and clean up to the appropriate soil and groundwater standard?*

The MCP at 310 CMR 40.0942(1)(b) states that when oil or hazardous material is present in, or is likely to migrate at potentially significant concentrations to an environmental medium in addition to soil and groundwater, then Method 1 alone shall not be used. Therefore, in the situation described above it must be demonstrated that the indoor air at the residence is not being affected by the release. How this determination is best made will depend upon the particular site circumstances, but may include soil gas studies, indoor air sampling or fate and transport modeling.

### 3.3 RESTRICTIONS ON THE USE OF METHOD 2

Method 2 allows for consideration of limited site-specific information and may be used in two different ways. First, Method 2 may be used to fill data gaps by creating additional Method 1 Standards where they do not currently exist. Method 2 may also be used to incorporate site-specific fate and transport information to modify existing Method 1 Standards. It is also possible to combine the two approaches in one risk characterization. Since a Method 2 risk characterization builds upon the Method 1 risk characterization, all the limitations and options for Method 1 discussed above also apply to Method 2. Specifically, Method 2 may be used at sites where the contamination is limited to soil and groundwater and there are no chemicals which bioaccumulate within the top two feet of soil.

#### 3.3.1 Development of Additional Method 1 Standards

The procedures for developing additional Method 1 Standards are set forth in the MCP at 310 CMR 40.0983 for groundwater standards and 40.0984 for soil standards. Section 6.3 of the guidance addresses the derivation of additional Method 1 Standards. Additional guidance is also available in the *Background Documentation for the development of the MCP Numerical Standards, April, 1994, Section 4.0 Groundwater and Section 5.0 Soil.*

### 3.3.2 Modification of Existing Method 1 Standards

The MCP allows for modification of existing Method 1 Standards. However, not all of the Method 1 standards may be modified. The Method 1 Standards which may be modified include:

- The Method 1 Soil Standards considering leaching potential (310 CMR 40.0985)
- The Method 1 GW-2 Standards considering volatilization potential (310 CMR 40.0986)
- The Method 1 GW-3 Standards considering the migration and discharge components (310 CMR 40.0987)

The Method 2 standards may be modified to incorporate site specific considerations. A more detailed discussion is presented in Section 6.4 of the guidance.

The Method 1 Standards which may not be modified include:

- The Method 1 Soil Standards based upon direct contact exposures (310 CMR 40.0985(6) Table 5)
- The Method 1 GW-1 Standards
- The Upper Concentration Limits ( 310 CMR 40. 0996(5) Table 6)

### 3.3.3 When Method 2 Alone May Be Used

Method 2 can be used as the sole form of risk characterization at sites where (a) the contamination is limited to the soil and groundwater and (b) there are no chemicals which bioaccumulate within the top two feet of soil.

### 3.3.4 When Method 2 May Be Used In Combination With Method 1

At sites with multiple chemicals and/or multiple exposures it is not necessary to modify the Method 1 standards for *all* the chemicals if only limited Method 2 modifications are appropriate. The risk assessor may use one or more Method 1 standards in combination with derived or modified Method 2 standards, as noted at 310 CMR 40.0982(5). For example, if Method 2 is used to derive a soil category S-1 standard for the chemical *methyl-ethyl-laccolith*, the Method 1 S-1 standards for the other chemicals at the site can be used without modification. Whenever some combination of Method 1 and Method 2 standards is used to characterize risk, the approach is described as a Method 2 risk

characterization, and the appropriate box would be checked on the Response Action Outcome Statement.

### 3.3.5 When Method 2 Can Be Used In Combination With Method 3

For sites which do not meet the criteria for using Method 2 alone, Method 2 may be used in combination with risk characterization Method 3 under the same limited circumstances that Method 1 can be used with Method 3 (See discussion, Section 5.0). The risk assessor could also choose to employ Method 3 alone to characterize the risk.

### 3.3.6 When Method 2 Is Not An Option

Method 2 is not an option and cannot be used at sites where all or some of the contamination present at the site is located in an environmental medium which is not soil or groundwater (unless human exposures to such contamination is minor as described in Section 5.0). In this case Method 3 must be used to characterize risk.

A Method 2 Risk Characterization should always be conducted in combination with a separate characterization of the risk of harm to safety posed by the contaminant conditions, as described in the MCP at 310 CMR 40.0960.

The detailed discussion in Section 5.0 of method applicability, soil and groundwater categorization, identification of exposure points, determination of exposure point concentrations, and risk characterization apply to Method 2 as well as Method 1, and will not be repeated in this section. The remainder of this section focuses on the differences between Method 1 and Method 2, which are related to the derivation and values of the standards used to characterize risk.

#### EXAMPLE

*A risk assessor has proposed conducting a Method 2 risk characterization at a disposal site. The only data available is Total Petroleum Hydrocarbon (TPH) concentrations in soil. The proposal includes modification of the Method 1 Standards based upon fate and transport considerations. Is this acceptable?*

There are several reasons why this approach may not be acceptable. Primarily the TPH values in Method 1 are based upon direct contact, not ability to leach and therefore can not be modified. Also, the TPH values do not assess BETX or PAH concentration, therefore it may not be appropriate to base the entire assessment on TPH data only.

### 3.4 RESTRICTIONS ON THE USE OF METHOD 3

There are no limitations on the Method 3 risk characterization. The MCP allows the use of site-specific risk assessment to evaluate any disposal site. It is important to note that when Method 3 is used to evaluate one or more human exposure pathways, it must be used for the entire risk assessment. More specifically, Method 1 and Method 2 cannot be used to evaluate risk from groundwater and soil at a site where Method 3 is applied to air exposures - the Method 1 (and thus Method 2) standards are not applicable and cannot be used in a method 3 assessment (310 CMR 40.0993(3)). This is not a "limitation" on the use of Method 3 because if contamination is present in media beyond soil and groundwater, Method 3 is the appropriate method to be used in the risk characterization.

#### EXAMPLE

*An underground storage tank has leaked gasoline into soil and groundwater. The tank is located 100 feet upgradient of a pond. To date no environmental sampling has been conducted in the pond to test surface water and sediments for the possible presence of gasoline. The responsible party has proposed conducting a Method 1 risk characterization for the soil and groundwater contamination. Is this an appropriate approach?*

No, not at this point. Given the proximity of the release to the pond the possibility of impacts on the pond should be addressed. If the surface water or sediments are contaminated, and soil and groundwater contamination does not "predominate", then it is best to use Method 3 to evaluate all the affected media at the site.

### 3.5 RISK CHARACTERIZATION FOR PORTIONS OF A DISPOSAL SITE

A Response Action Outcome may be achieved and a Response Action Outcome Statement submitted for an entire site, disposal site, or a portion of a disposal site (310 CMR 40.1003(3)). The ability to achieve separate RAOs for portions of a site allows the expedited cleanup of areas which are more readily addressed: problems which are more complex or difficult to assess/remediate can be dealt with on a different schedule. RAOs for a portion of a disposal site may also be an attractive option in situations where the disposal site includes more than one property.

The general provisions for Response Action Outcome are described at 310 CMR 40.1003. An Class A or Class B RAO submitted to DEP must be supported by documentation that a level of No Significant Risk exists or has been achieved for the site or disposal site (310 CMR 40.1004). RAO Statements submitted for a portion of a disposal site may be problematic, as the fundamental risk management criteria of the MCP are expressed as limits on cumulative risk (i.e., the risk to a receptor received from all applicable exposure pathways and all chemicals). Therefore, by breaking up a site into discrete areas and assessing them separately, the cumulative impact of the contamination may not be adequately addressed.

Several questions have been raised about how to conduct risk characterizations for portions of a disposal site:

- *Must the same risk characterization Method be used for each portion of the site?*
- *Must the last RAO submitted for a site include a risk characterization for the entire site?*
- *How is the concept of Cumulative Risk considered for a site achieving multiple RAOs?*

In order to answer these questions, the Department recommends the following approach:

The method of risk characterization used to support a Response Action Outcome for a portion of a disposal site should be selected using the criteria set forth in 310 CMR 40.0942 and may be different from the risk characterization method used for other portions of the same disposal site.

- ▶ If Methods 1 or 2 are used to characterize risk for that portion of a disposal site no further consideration of cumulative risk is needed. Note that the Method 1 standards were set at levels which would be generally protective of multi-chemical, multi-pathway exposures.
- ▶ If Method 3 is used to characterize risk at one or more portions of the disposal site particular attention must be paid to how the Method 3 assessment is conducted and how the results are interpreted in order to insure that the Cumulative Receptor Risk Limits are met for the entire site or disposal site. In other words, Method 3 risk characterizations conducted in support of an RAO for a portion of a disposal site must still address the issue of Cumulative Receptor Risk. Specifically, each Method 3 risk characterization should either:
  - evaluate all potential exposure pathways for each identified receptor of concern, even those exposures occurring at points beyond the portion of the site considered in the RAO, or

- demonstrate that the risks from the exposure pathways evaluated are sufficiently below the Cumulative Receptor Risk Limits that the exposures associated with this portion of the disposal site would not be significant even if the same receptor were exposed to contamination at other portions of the same site.

In the first Method 3 option above, the risk assessor must identify all potential exposure points for each receptor (310 CMR 40.0924). If all the receptors' exposure points happen to be located within the portion of the disposal site addressed in the RAO, then the Method 3 assessment would not differ from a standard assessment. If one or more exposure points are located outside the portion of the disposal site addressed in the RAO then the risk assessor must consider the exposures occurring at those locations. Some coordination of site assessment is needed since this approach would likely require access to analytical data describing contaminant concentrations at those locations.

Under the second Method 3 option above, the approach is similar to screening of exposure pathways described in Section 3.2.2 of this guidance: the exposures from this portion of the disposal site must be relatively minor, meaning that the cumulative risks associated with those exposures should be at least an order of magnitude below the MCP cumulative risk limits (i.e., a cumulative excess lifetime cancer risk no greater than one-in-one million, and a cumulative hazard index no greater than 0.1.) If the risks associated with this portion of the disposal site are greater than those levels, then the additional exposures experienced by that receptor must be evaluated (the first Method 3 option) using the cumulative risk approach.

This approach for characterizing risk to support a Response Action Outcome for a portion of a disposal site allows different risk characterization methods to be used for the different RAOs, it eliminates the need for a final "comprehensive" risk characterization of the site after all the RAOs for the different portions have been submitted, and this approach addresses the regulatory requirement to meet the Cumulative Receptor Risk Limit.

### 3.6 NOTATION ON THE RAO FORM

The Response Action Outcome (RAO) Statement & Downgradient Property Status Transmittal Form (BWSC-104) requires the person submitting the form to identify the risk characterization method used. Section F of the form provides a simple check list to identify the Risk Characterization Method(s) used and the applicable soil and groundwater categories at the site. The appropriate boxes should be checked.

Remember that there are only limited circumstances under which more than one Risk Characterization Method will be used to support a single RAO - most RAO Statements will have just one box checked. It would be appropriate to mark two boxes, Methods 1 and 3, for example, if Method 1 was used to conduct the human health risk characterization and Method 3 was used to address the environmental risk characterization.

It is not necessary to check a Risk Characterization Method box if the concentrations of all the oil or hazardous material at the site are consistent with background, since no risk characterization is required at such sites (310 CMR 40.0901(3)). These sites are eligible for a Class A-1 or Class B-1 RAO.

Since more than one soil category and more than one groundwater category may apply at a given site, all the applicable soil and groundwater categories within the area covered by the RAO should be checked. Note that the applicable categories are checked, not the category of the standards actually achieved. For example, additional remediation may be conducted to achieve S-1 standards at sites where soil is actually categorized as S-2 in order to avoid having to record an Activity and Use Limitation. The S-2 box should be checked on the RAO form because that is the actual applicable category, even though the S-1 standards were achieved.

## 4.0 CHARACTERIZATION OF RISK OF HARM TO SAFETY

This section describes the evaluation of the risk of harm to safety, including a discussion of the definition of "risk to safety", criteria to be used to evaluate safety risks, and some descriptions of situations that are presumed to constitute safety hazards. It is anticipated that most evaluations of risk to safety will use qualitative rather than quantitative criteria.

A characterization of risk to safety is required at all sites at which a Subpart I risk characterization is performed (310 CMR 40.0941(2)). The risk to safety must be looked at separate from, and in addition to the Method 1, 2, or 3 evaluation of risk of harm to health, public welfare, and the environment. Typically, the assessment of safety issues should be presented as a separate chapter in the risk characterization report.

The scope and level of detail of a safety evaluation is expected to vary from site to site, and should be sufficiently detailed to conclude whether a safety problem related to the release or threat of release of oil or hazardous material exists at the site. The individual or individuals performing the evaluation of risk of harm to safety should follow the "Response Action Performance Standards" (RAPS), which are discussed in 310 CMR 40.0191, in determining the appropriate level of effort.

The Massachusetts Contingency Plan (310 CMR 40.0960) requires the characterization of the risk of harm to safety at a disposal site when using any of the risk assessment methods. Any identified safety risks must be considered when determining the need for remediation. Remediation may be required based upon the risk of harm to safety, even if no further remedial response actions are necessary based upon human health considerations. It must also be stressed that in characterizing the risk of harm to safety one must look not only at releases which have occurred, but also at the "threat of a release".

The purpose of evaluating the risk of harm to safety is to identify conditions which have resulted or may result in a release of oil and/or hazardous material currently or in the foreseeable future that will pose a threat of physical harm or bodily injury to people. The general definition of harm to safety in the Massachusetts Contingency Plan states that a level of no significant risk to safety exists or has been achieved if the conditions at the disposal site which are related to a release of oil and/or hazardous material do not currently and will not in the foreseeable future pose a threat of physical harm or bodily injury to people.

#### 4.1 CONDITIONS CONSTITUTING A RISK OF HARM TO SAFETY

Some common examples of conditions that constitute a risk of harm to safety are as follows: rusted or corroded drums or containers; weakened berms; the threat of fire or explosion, including the presence of explosive vapors resulting from the release of oil and/or hazardous material; reactive chemical(s) stored or disposed of in a way that does not reasonably preclude uncontrolled reactions; unsecured pits, ponds, lagoons or other dangerous structures; any uncontained materials which exhibit the characteristics of corrosivity, reactivity, flammability, or are considered infectious materials as described in 310 CMR 40.0347; and the presence of ionizing or nonionizing radiation.

There may be conditions present at a site that are not related to the release of hazardous material and would, therefore, not be considered a risk to public safety under M.G.L. Ch.21E in most instances. Such site conditions may include the presence of metal shards or other sharp objects or the presence of a structurally unsound building at a site. It should be noted that there may be uncommon circumstances which could be considered to pose a risk to safety under c.21E. An example is the presence of sharp objects or syringes at a disposal site which have the potential to increase the exposure of a receptor to the oil or hazardous material (including infectious material pursuant to 310 CMR 40.0347(5)) present at the site through a puncture wound or similar injury.

#### 4.2 DEFINITIONS OF CHARACTERISTICS OF HAZARDOUS MATERIALS WHICH MAY POSE A RISK OR HARM TO SAFETY

In this section particular characteristics of hazardous materials, those which pose a risk of harm to safety, will be discussed more in depth. How one determines if a material is flammable/ignitable, corrosive, reactive, or infectious is outlined in section 40.0347 of the Massachusetts Contingency Plan.

The definition of *flammability/ignitability* is discussed in section 310 CMR 40.0347(1) of the MCP. A material is considered flammable/ignitable if a representative sample exhibits any of the following characteristics: liquid with a flash point of less than 60 degrees Celsius/140 degrees Fahrenheit; a non-liquid which is capable under standard temperature and pressure of catching fire through friction, absorption of moisture or spontaneous chemical changes and, when ignited burns so vigorously and persistently that it creates a hazard; a compressed gas that is ignitable or an oxidizing agent. Methods for testing for determining flash point of liquids and the ignitability of compressed are outlined in section 310 CMR 40.0347(1)(b) and (c).

*Corrosivity* is discussed in section 310 CMR 40.0347(2) of the MCP. A material is considered corrosive if a representative sample exhibits any of the following properties: it is aqueous and has a pH equal to or less than 2.0 or equal to or greater than 12.5; it is a liquid and

corrodes steel (type SAE 1020) at a rate greater than 6.35 mm per year at a test temperature of 55 degrees Celsius; or it is a liquid that causes visible destruction or irreversible alterations in mammalian skin tissue at the site of contact. Methods for testing pH and determining the rate of corrosion are outlined in section 310 CMR 40.0347(2)(b) and (c).

**Reactivity** is discussed in section 310 CMR 40.0347(3) of the MCP. A material is considered reactive if a representative sample exhibits any of the following properties: it is normally unstable and readily undergoes violent changes without detonating; it reacts violently with water; it forms potentially explosive mixtures with water; when mixed with water it generates toxic gases, vapors, or fumes in a sufficient quantity to pose a risk to safety; it is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement; it is readily capable of detonation or explosive decomposition or reaction at a standard temperature and pressure; or is defined as a forbidden explosive, or a Class A or Class B explosive.

**Infectious materials**, which pose a risk of harm to safety, are defined in section 310 CMR 40.0347(5) of the MCP. Infectious materials are those materials, that, because of their infectious characteristics may: cause, or significantly contribute to an increase in mortality or an increase in serious irreversible or incapacitating reversible illness; or pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of or otherwise managed. Infectious materials are hazardous materials subject to the provisions of the MCP, unless specifically excluded from regulation.

#### **4.3 APPLICABLE OR SUITABLY ANALOGOUS STANDARDS, GUIDELINES, AND POLICIES**

At a minimum, current and reasonably foreseeable disposal site conditions and conditions in the surrounding environment must be compared to applicable or suitably analogous safety standards, guidelines, and policies when characterizing the risk of harm to safety. When assessing the flammability/ignitability of an oil or hazardous material, ORS recommends applying National Institute for Occupational Safety and Health (NIOSH) standards for determining the Lower Explosive Limits (LELs) of compounds in air.



## 5.0 METHOD 1

The specific regulations concerning the Method 1 risk characterization procedure are found at 310 CMR 40.0970 of the Massachusetts Contingency Plan. Readers are reminded that general requirements applicable or potentially applicable to all risk characterizations are found in 310 CMR 40.0900 through 40.0960, collectively referred to as Subpart I. Readers are urged to refer to the MCP if there are questions about the specific regulatory requirements.

The Method 1 approach was developed to provide a straightforward comparison of site conditions to promulgated standards to evaluate the risk of harm to health, public welfare and the environment<sup>1</sup>. The use of promulgated standards in the risk characterization has many benefits:

- The assessment process is simplified. The risk assessor does not need to quantitatively evaluate receptor exposures, nor explicitly estimate risk.
- There is greater certainty that the requirements of the regulations have been achieved. The "No Significant Risk" levels are stated explicitly and in terms that are familiar to the lay public and site assessment specialists alike: concentrations of the contaminant in soil and groundwater.
- There is greater consistency in remedial decisions. Because the No Significant Risk requirements are explicit, there is little opportunity for varied interpretation from site-to-site.
- The cost and time required for the risk characterization is reduced, freeing resources to be used for remediation.

Promulgated standards are generic by nature, and use of the MCP Method 1 standards provides very limited site-specific flexibility. By choosing to use the Method 1 risk characterization approach the risk assessor is implicitly accepting the assumptions identified by MADEP for the development and use of the standards.

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<sup>1</sup> - The risk of harm to safety must be evaluated separately, as described in Section 4.0 of this guidance document.

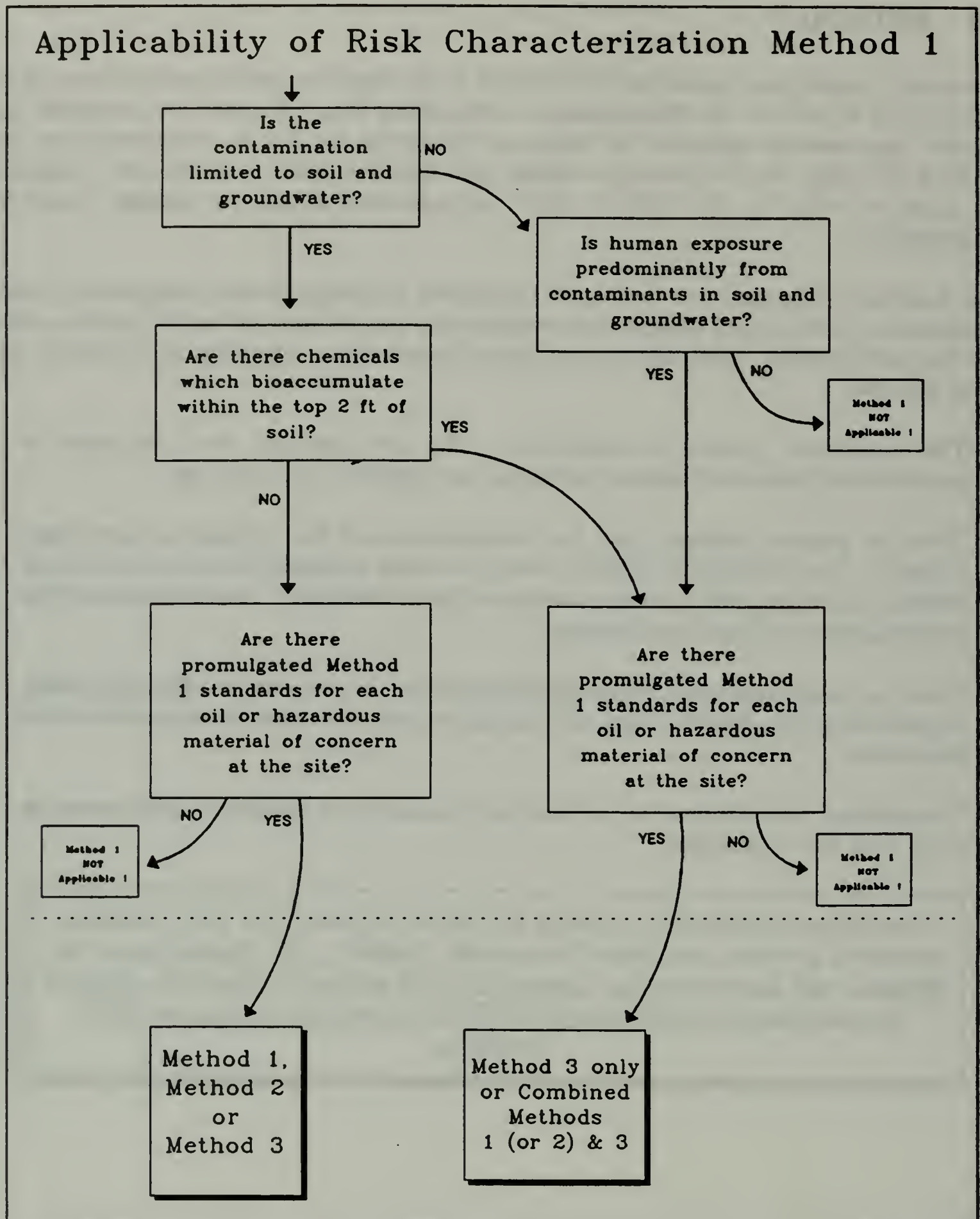


Figure 5.1

Because of the generic nature of the Method 1 standards, this approach is not available to all sites. Method 1 is also not *required* at sites where it is an available option as the risk assessor may chose to conduct either a Method 2 or Method 3 risk characterization in lieu of Method 1 if he/she believes that the benefits of such a site-specific approach outweigh those described above.

## 5.1 APPLICABILITY

When determining whether Method 1 can be used to characterize the risk of harm to health, public welfare and the environment, the risk assessor should scrutinize criteria found at 310 CMR 40.0942. It is expected that Method 1 will be an option at the majority of c.21E sites. At certain sites, however, the risk assessor will have to supplement the Method 1 risk characterization with some form of a Method 3 assessment, while at other sites Method 1 will not be an available option. This section describes the circumstances under which Method 1 may or may not be employed. Method 1 is never required for particular sites. It is up to the risk assessor to determine the appropriate risk characterization approach from among the methods identified as applicable to the site.

## 5.2 GENERAL APPROACH

A Method 1 risk characterization always includes the following steps, although the scope and level of effort of the risk characterization will depend upon the complexity of the disposal site and the response action being taken.

- Information gathered as part of the site investigation is used to determine the nature and extent of oil or hazardous material present and the extent of contamination.
- Information gathered as part of the site investigation is used to identify background concentrations and to determine the contaminants of concern for the risk characterization.
- The applicability of Method 1 is affirmed.
- Knowledge about the disposal site and the surrounding area is used to categorize the soil and the groundwater.
- The soil and groundwater categories are used to identify the Method 1 standards which are applicable to the disposal site.
- Chemical concentrations and their spatial distribution are used to identify exposure points (including hot spots) and exposure point concentrations.

- The exposure point concentrations are compared to the applicable Method 1 standards.
- The risk of harm to safety is characterized.
- A conclusion is drawn as to whether a condition of no significant risk of harm to health, safety, public welfare or the environment exists or has been achieved at the disposal site, with or without Activity and Use Limitations.
- Activity and Use Limitations (if necessary) to limit future use of the site are described.

Note that Method 1 represents a streamlined approach to the risk characterization process, not to the site assessment process; an adequate knowledge of the site and the contamination present is still necessary to employ this approach. Of course, the resources required for the site assessment will vary from site-to-site, depending upon the nature and complexity of the release under investigation: the scope and level of effort required for the site investigation and the risk characterization will be determined using the professional judgement of the investigator considering site-specific circumstances.

The risk assessor should keep in mind that the Method 1 approach does not evaluate potential Imminent Hazards which may be present at the disposal site. If site conditions suggest that a quantitative Imminent Hazard Evaluation be conducted for the disposal site, the regulations found at 310 CMR 40.0950 and the guidance provided in Section 10.0 of this document must be considered. Such evaluations are not routinely required at all disposal sites.

Information concerning the site, nature and extent of contamination, soil and groundwater categories, exposure point concentrations, applicable Method 1 standards and conclusions of the risk characterization must be provided to MADEP in the documentation which supports the risk characterization. The documentation of the risk characterization may be one or more chapters of another submittal to the Department or it may be presented as a separate document.

The remaining sections of this chapter will describe in more detail the general steps outlined above.

### 5.3 DETERMINING THE NATURE AND EXTENT OF CONTAMINATION

Section 2.2 of this document presents general guidance on determining the nature, extent, distribution and magnitude of contamination at disposal sites for the purpose of risk characterization. The MCP (310 CMR 40.0904) directs the investigator to collect sufficient site and contaminant information to support the risk characterization. Knowledge about the

nature and extent of contamination is used to determine whether a Method 1 risk characterization is appropriate for the disposal site, and whether, pursuant to Method 1, the contamination at the site poses No Significant Risk.

At the start of the risk characterization process the investigator should know what chemicals are present, the environmental media in which the chemicals are located, the concentrations of each chemical in each medium and the spatial distribution of the contaminants. In addition, the migration potential of each chemical should be considered to determine the likelihood of the oil or hazardous material spreading within existing contaminated media (e.g., growing plumes of chlorinated hydrocarbons) or being transferred to an environmental medium which is currently unaffected by the site (e.g., future discharge of groundwater to a surface water body). If contaminant concentrations are likely to increase at a current or foreseeable exposure point then the risks associated with those estimated future concentrations must also be characterized. Chemical-specific information which may be relevant to the risk characterization includes the factors listed at 310 CMR 40.0904(3), including environmental fate and transport characteristics, mobility, persistence, volatility and potential for bioaccumulation.

## METHOD 1 ASSESSMENTS AT CYANIDE SITES

When cyanide is present in accessible soil at a site, an imminent hazard evaluation of the potential risk from a one-time dose should be done automatically, regardless of which risk assessment method is being used. Of all of the chemicals commonly detected at disposal sites, cyanide is the only one which could pose a significant health risk from a one-time exposure to concentrations that are often found in the environment. Although acute exposures to some other hazardous materials could pose a health risk at some level, the concentrations at which acute exposures are of concern are much higher than levels typically found in the environment.

With cyanide, the risk estimate for a one time exposure may exceed the risks from long term exposures. There are two reasons for this paradox. First, one-time risk estimates are based on the highest concentration detected, while long-term risk estimates and comparisons to Method 1 Standards use average soil concentrations. Second, because cyanide is metabolized and cleared from the body relatively quickly, exposures which occur in a short period of time will have a greater effect than exposure to the same total amount received over a longer period of time - even if the time difference is a matter of hours. The Method 1 Standard for cyanide is the same as the concentration above which a one-time dose could pose a significant risk. Therefore, comparing an average soil concentration to the Method 1 Standard does not protect against potential health risks from a one-time dose.

Overall confidence in the assessment and remediation process is directly related to the site characterization: if the investigator fails to analyze a medium likely to be contaminated by the chemicals at the site, if the focus of the evaluation is the source area to the exclusion of contamination which has migrated off the property, or if too few samples were taken (or taken in dubious locations, or analyzed following the wrong methodology) to sufficiently

describe the nature and extent of contamination, then conclusions drawn from the risk characterization will be meaningless.

#### **5.4 IDENTIFICATION OF CONTAMINANTS OF CONCERN (COC)**

Once the oil or hazardous material present at the site have been identified for each contaminated environmental medium, the process of selecting the contaminants of concern may proceed. The contaminants of concern are those chemicals which are carried through the risk characterization process. General guidance on the selection of contaminants of concern is provided in Section 2.4 of this document. At some sites there may be a single contaminant of concern, while the list of COCs may be lengthy at others.

The discussion in Section 2.4 identifies three basic criteria used to eliminate a chemical from further consideration in the risk assessment: (1) the chemical is present at a very low frequency of detection and at very low concentration, or (2) the chemical is present at a level consistent with "background", or (3) the chemical is a field or laboratory contaminant. The reader is also referred to the "background" discussion presented in Section 2.3, including the identification of background levels at a site and the comparison of site concentrations to background conditions. The process of identifying contaminants of concern is the same for Method 1 as for a site-specific risk assessment.

#### **5.5 AFFIRMATION OF METHOD 1 APPLICABILITY**

The risk characterization report should demonstrate that the use of Method 1 to characterize risk at the site is appropriate (310 CMR 40.0971(4)). The Department understands that there is a bias towards the use of Method 1 due to its simplicity and ease of use which could result in the use of Method 1 standards to situations where they do not apply. By requiring that the method selection process be documented in the risk characterization report, the regulations compel the risk assessor (and/or LSP) to think through the applicability criteria at every site. Section 5.1 of this document reviews the applicability of Method 1 at c.21E disposal sites.

#### **5.6 SOIL AND GROUNDWATER CATEGORIZATION**

General guidance on the categorization of soil and groundwater is provided in Section 2.1.5 of this document, and the regulations pertinent to categorization are found in the MCP at 310 CMR 40.0930. The current and foreseeable use of the soil and groundwater determine the categories (S-1, S-2 and/or S-3 for soil, GW-1, GW-2 and/or GW-3 for groundwater) which apply at the site.

Soil is categorized based upon its accessibility (depth), the age of potential receptors (child or adult) at the site, the frequency at which the receptors visit the location and the nature (intensity) of the activities that occur at the location. These factors allow the soil to be described as having high, medium or low exposure potential: the soil categories represent an exposure gradient, where accessibility, the presence of children, frequent use and intense activity indicate a higher exposure potential, while soil at depth, limitations on access for children, infrequent and passive use all indicate lower potential for exposure. Often the use of properties in the surrounding area (e.g., adjacent land) may give an indication of potential exposures on the property under investigation, and thus they should also be considered (e.g., a property located next to an elementary school is likely to be routinely visited by school-age children. Due to the various factors which go into the categorization of soil, it will be common to find more than one soil category present at the site: the surficial soil may be considered S-1, for example, while the soil located more than three feet below the surface could be S-2. A property supporting multiple uses (a light manufacturing facility with an in-house day care center, for example) could have the surficial soil categorized as S-1 in the area of the day care while the surficial soil in other areas may be S-3. [It should be obvious, however, that a specific area cannot be in two soil categories at the same time.]

Groundwater is categorized based upon its current and/or future use as drinking water (GW-1), its potential to act as a source of volatile material to indoor air (GW-2), and its potential to discharge material to surface water (GW-3). Groundwater may be, at the same time, GW-1, GW-2 and GW-3 as these exposures are not mutually exclusive. In fact, all groundwater is categorized as GW-3. The groundwater at the site may also be GW-2 and/or GW-1, depending upon site-specific factors. Thus, the potential combinations of groundwater categories are:

- GW-3 only,
- GW-1 and GW-3,
- GW-2 and GW-3, or
- GW-1 and GW-2 and GW-3.

*It is not possible for groundwater to be GW-1 alone or GW-2 alone.*

One additional factor to consider when evaluating groundwater is the potential migration of the contaminated water into an area with a different groundwater category.

Note that both the current and future use of the land and groundwater must be considered in the categorization process. Thus, in categorizing soil as S-2 or S-3, it is implied that the potential future exposures to that soil are restricted in some manner (by depth to the soil, access to the site, etc.). Under Method 1 only S-1 soils can be described as "unrestricted" for any use. For groundwater, the consideration of the future use of the groundwater as a drinking water source (GW-1) and as a future source of discharge to surface water (GW-3)

are built into the categorization criteria. It is only for the GW-2 category that future changes in the use of the property could effect the groundwater category (i.e., constructing a building where there is presently no structure.)

All soil and groundwater must be categorized. There is no soil or groundwater which does not fit into one of the established categories.

## **5.7 IDENTIFICATION OF APPLICABLE METHOD 1 SOIL AND GROUNDWATER STANDARDS**

The categorization process summarized above is the basis for selecting the applicable soil and groundwater standards under Method 1. The regulations pertinent to the applicability of those standards are found at 310 CMR 40.0974 and 310 CMR 40.0975, for groundwater and soil, respectively.

The Department has published (MADEP, 1994) a detailed description of the development of the MCP Method 1 Standards.

The documentation which supports the risk characterization should include a list of the MCP Method 1 groundwater and soil standards determined to be applicable for the site (310 CMR 40.0973(5)).

### **5.7.1 Groundwater**

The Method 1 groundwater standards are listed at 310 CMR 40.0974(2), in Table 1 of Subpart I. A portion of that table is presented as Figure 5-2 for illustration purposes. The table of groundwater standards consists of five columns:

- the name of the oil or hazardous material,
- the CAS number of the oil or hazardous material,
- the GW-1 standard for the oil or hazardous material,
- the GW-2 standard for the oil or hazardous material, and
- the GW-3 standard for the oil or hazardous material.

As previously described, more than one groundwater category can apply to the groundwater at a site, and *all* groundwater is considered to be GW-3. Thus the standards listed in the last column (GW-3 Standard) of Table 1 (Figure 5-2) apply to the groundwater at all sites. In addition, the standards listed in column three (GW-1 Standard) and column four (GW-2 Standard) may also be applicable, depending upon site-specific factors. In the case when more than one category applies, for example, if the

groundwater at a site is GW-1, GW-2 and GW-3, then *all* the applicable standards must be considered, and the lowest applicable value would drive the risk characterization.

It is not true that GW-1 standards are always the lowest groundwater standards.

Because the groundwater categories look at markedly different exposure routes, any of the three categories may be the most sensitive, depending upon the chemical. In general, GW-3 is the most stringent category for pesticides and some metals, while the GW-2 standards may be lowest for some halogenated volatile chemicals.

FIGURE 5-2

310 CMR 40.0974(2)

TABLE 1

MCP Method 1 GROUNDWATER STANDARDS  
APPLICABLE IN AREAS WHERE THE GROUNDWATER  
IS CONSIDERED TO BE ONE OR MORE OF THE  
FOLLOWING CATEGORIES PER 310 CMR 40.0932

Oil and/or hazardous Material	CAS Number	GW-1 Standard	GW-2 Standard	GW-3 Standard
		$\mu\text{g/liter}$ (ppb)	$\mu\text{g/liter}$ (ppb)	$\mu\text{g/liter}$ (ppb)
ACENAPHTHENE	83329	20	NA	2,000
ACENAPHTHYLENE	208968	300	NA	2,000
ACETONE	67641	3,000	50,000	50,000
ALDRIN	309002	0.5	0.5	9
ANTHRACENE	120127	600	NA	600

This table is presented as an example of the *format* in the regulations. Consult the actual table in the regulations for current standards.

### 5.7.2. Soil

The Method 1 soil standards are listed at 310 CMR 40.0975(6) in the MCP. The soil standards are organized in three tables (Subpart I Tables 2, 3 and 4), and a portion of each is presented for illustration purposes in Figures 5-3, 5-4 and 5-5, respectively. Each table is specific to a single soil category: Table 2 contains all the MCP Method 1 Category S-1 standards, Table 3 contains all the Method 1 Category S-2 standards, and Table 4 contains all the Method 1 Category S-3 standards. Each table is made up of 5 columns:

- the name of the oil or hazardous material,
- the CAS number of the oil or hazardous material,
- the soil standard for soil overlying a GW-1 aquifer,
- the soil standard for soil overlying a GW-2 aquifer,
- the soil standard for soil overlying a GW-3 aquifer.

Figure 5-3

310 CMR 40.0975(6)(a)				
TABLE 2				
MCP Method 1: SOIL CATEGORY S-1 STANDARDS				
APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:				
Oil and/or hazardous Material	CAS Number	S-1 SOIL & GW-1	S-1 SOIL & GW-2	S-1 SOIL & GW-3
		µg/g (ppm)	µg/g (ppm)	µg/g (ppm)
ACENAPHTHENE	83329	20	1,000	1,000
ACENAPHTHYLENE	208968	100	100	100
ACETONE	67641	3	60	60
ALDRIN	309002	0.03	0.03	0.03
ANTHRACENE	120127	1,000	1,000	1,000
This table is presented as an example of the <i>format</i> in the regulations. Consult the actual table in the regulations for current standards.				

The soil standards were derived in consideration of potential direct contact exposures (incidental soil ingestion and dermal contact) and considering the potential for the oil or hazardous material to leach from the soil and contaminate the underlying groundwater. Thus the allowable level of a chemical in soil depends, in part, upon the allowable level of the chemical in the groundwater. If the groundwater at the site is determined to be in more than one groundwater category (e.g., both GW-2 and GW-3) then more than one

soil standard will apply (e.g., both S-1/GW-2 and S-1/GW-3) and the lowest of the applicable standards will drive the risk characterization.

Figure 5-4

310 CMR 40.0975(6)(b)				
TABLE 3				
MCP Method 1: SOIL CATEGORY S-2 STANDARDS				
APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:				
Oil and/or hazardous Material	CAS Number	S-2 SOIL & GW-1	S-2 SOIL & GW-2	S-2 SOIL & GW-3
		µg/g (ppm)	µg/g (ppm)	µg/g (ppm)
ACENAPHTHENE	83329	20	2,500	2,000
ACENAPHTHYLENE	208968	100	2,500	800
ACETONE	67641	3	60	60
ALDRIN	309002	0.04	0.04	0.04
ANTHRACENE	120127	1,000	2,500	1,000
This table is presented as an example of the <i>format</i> in the regulations. Consult the actual table in the regulations for current standards.				

Figure 5-5

310 CMR 40.0975(6)(c)				
TABLE 4				
MCP Method 1: SOIL CATEGORY S-3 STANDARDS				
APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:				
Oil and/or hazardous Material	CAS Number	S-3 SOIL & GW-1	S-3 SOIL & GW-2	S-3 SOIL & GW-3
		µg/g (ppm)	µg/g (ppm)	µg/g (ppm)
ACENAPHTHENE	83329	20	5,000	2,000
ACENAPHTHYLENE	208968	100	2,500	800
ACETONE	67641	3	60	60
ALDRIN	309002	0.1	0.1	0.1
ANTHRACENE	120127	1,000	5,000	1,000
This table is presented as an example of the <i>format</i> in the regulations. Consult the actual table in the regulations for current standards.				

Interestingly, the leaching-to-groundwater pathway is often more sensitive (produces a lower allowable soil concentration) than the direct contact exposure pathway. As a result, many of the standards for S-1, S-2 and S-3 soil overlying a particular groundwater category will be the same value: for example the S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards for acetone in the tables above are all 3  $\mu\text{g/g}$ . Thus, while one would expect the allowable acetone soil concentration to increase as the soil category increases (S-1 soil to S-3 soil, or high to low exposure potential), this does not occur.

## 5.8 IDENTIFICATION OF EXPOSURE POINTS AND EXPOSURE POINT CONCENTRATIONS (Including Hot Spots)

The regulations which address the identification of exposure points and the development of exposure point concentrations for Method 1 risk characterizations are found at 310 CMR 40.0973(3) and (4). More general discussion of these terms appears at 310 CMR 40.0924 and 40.0926.

### 5.8.1. Groundwater

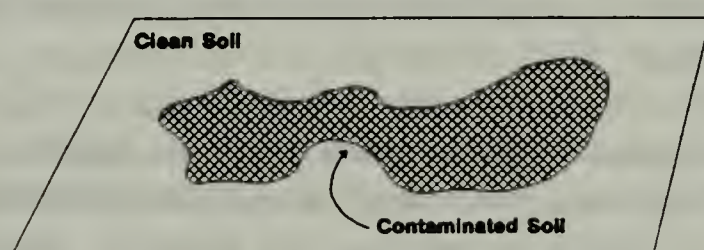
For groundwater, the MCP defines the exposure point to be used for a Method 1 risk characterization as *"...the wellhead and/or nearest tap of a well screened within the horizontal and vertical distribution of the oil or hazardous material in the groundwater. Existing water supply wells and monitoring wells shall be considered current or potential Exposure Points..."* (310 CMR 40.0973(3)(a)). Thus each well located within the contaminated area is considered either a current or future exposure point.

The exposure point concentrations for groundwater are thus easily identified as the concentrations reported from each water supply or monitoring well, as described in 310 CMR 40.0973(4)(b). Limited averaging over time of these reported concentrations would be consistent with the statement at 310 CMR 40.0926 that exposure point concentrations shall be arithmetic averages providing a conservative estimate of the concentration at the exposure point, although averaging of data across wells (across exposure points) is not acceptable for Method 1. The quality of data collected in the past and trends in the data should be assessed to determine whether a temporal average is appropriate to yield a conservative estimate. There are, of course, situations when the maximum concentration reported (or an upper percentile) is appropriate, including the evaluation of acute exposures, the evaluation of chemicals associated with lethal or severe health effects, evaluations performed with insufficient data, or conservative screening assessments.

## 5.8.2 Soil

In the MCP the exposure points for soil are defined by *"the vertical and horizontal distribution of the material in soil in combination with the soil category(ies) determined to be applicable"* (310 CMR 40.0973(3)(b)). Thus, in order to identify the soil exposure points for a Method 1 risk characterization the investigator must know the extent of contamination and how the soil would be categorized at the site. Figures 5-5 through 5-10 describe situations which may arise when identifying soil exposure points.

Figure 5-6



The Exposure Point Would Include Only The Contaminated Soil

First, Method 1 soil Exposure Points encompass only continuous areas of contaminated soil and do not include clean soil. Thus, the boundary of an Exposure Point is no larger than the extent of the soil contamination at the site. Figure 5-6 illustrates that only the area of contamination would be considered the soil Exposure Point.

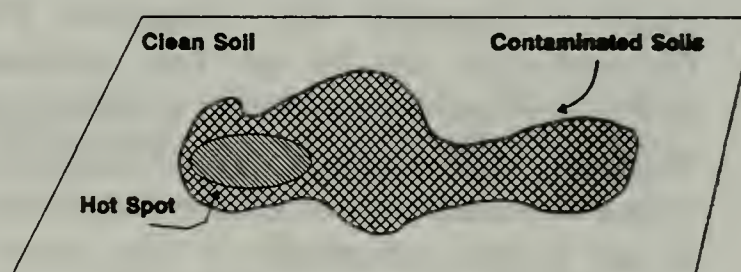
Second, hot spots are specifically identified (310 CMR 40.0924(2)) as distinct exposure points. The identification of a *"hot spot"* is discussed in more detail in Section 2.2.3 of this document, but is defined within the MCP as a discrete area with substantially higher contamination relative to the surrounding area. Thus, if a hot spot exists with a larger area of contamination, there would be at least two Exposure Points identified: the hot spot and the area of more generalized contamination. Figure 5-7 illustrates a hot spot as a distinct exposure point.

Third, if the area of contaminated soil is not contiguous, then the discrete areas of contaminated soil which exist at the site are treated as a separate Exposure Point. Figure 5-8 illustrates this point.

Finally, if the boundary of a soil category bisects the contaminated area, then the soil which falls within each soil category is treated as separate Exposure Points. Figure 5-9 illustrates how this may occur.

It is also important to remember that the exposure points exist in three dimensions. Figures 5-6 through 5-9 present exposure points in two dimensions for clarity, but there is a depth component

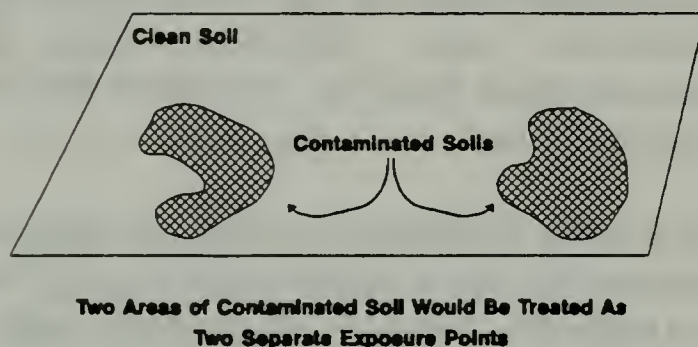
Figure 5-7



A Hot Spot Within An Area Of Contaminated Soil Is Treated As A Distinct Exposure Point

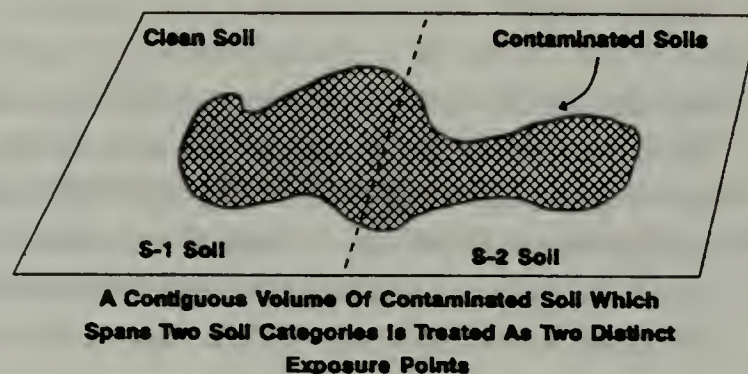
as well, which is why the term "volume" is used in the MCP in the discussion of Method 1 exposure points (310 CMR 40.0973(3)(b)). Thus, a volume of contaminated soil five feet below ground would be considered a Method 1 Exposure Point, and that Exposure Point would not include the uncontaminated soil on the surface (See Figure 5-10). Multiple soil categories, hot spots and disconnected contamination would be considered in the same manner in three dimensions as they were described above.

Figure 5-8



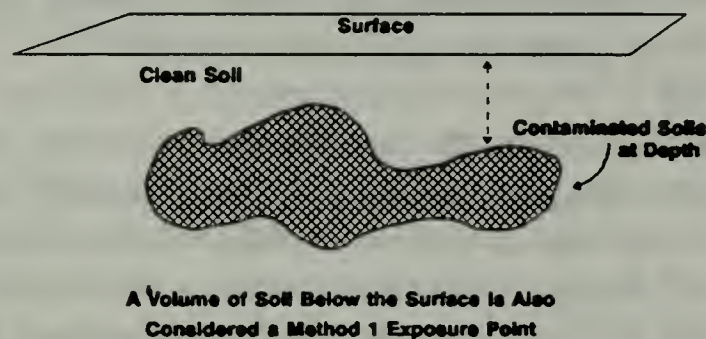
The exposure point concentrations for soil are representative concentrations for the oil or hazardous material within each exposure point. Typically the Exposure Point Concentration would be the arithmetic average of the contaminant concentration, although consideration should be given to using the maximum concentration reported or an upper percentile of the range of concentrations reported when the site data may not be adequate, when evaluating acute exposures, when evaluating chemicals associated with lethal or severe health effects or when performing screening assessments (310 CMR 40.0926(3)). Since the Method 1 exposure point is defined such that it excludes uncontaminated soil, analytical results

Figure 5-9



Soil at depth is considered an Exposure Point under Method 1 due to the potential for future excavation and contact. Since such potential future exposures are part of the basic premise of Method 1 (310 CMR 40.0972), the risk assessor cannot eliminate this exposure pathway (determine that such exposure would never occur, and that the soil at depth does not constitute an Exposure Point) when using Method 1 to characterize risk, although such site-specific risk assessment may be appropriate under a Method 3 assessment.

Figure 5-10



from "clean" areas of the site should not be incorporated into the exposure point concentration.

## 5.9 CHARACTERIZING RISK UNDER METHOD 1

Having identified the Method 1 standards applicable to the site (Section 5.7) and the site Exposure Points and Exposure Point Concentrations (Section 5.8), the risk characterization is simply the comparison of the exposure point concentrations to the applicable Method 1 standards. As described in the MCP (310 CMR 40.0973(7)), *"a condition of no significant risk of harm to health, public welfare or the environment exists if no Exposure Point Concentration is greater than the applicable MCP Method 1 Soil or Groundwater Standard"*. The report which documents the risk characterization should include tables ordered by environmental medium and exposure point comparing the exposure point concentrations to the applicable MCP Method 1 standards. An example of such a table is presented in Figure 5-11.

### 5.9.1 Characterizing Risks Using TPH Data

#### Using the Method 1 Standard for Total Petroleum Hydrocarbon

Total Petroleum Hydrocarbon, or TPH, is one of the one hundred and seven chemicals (or groups of chemicals) for which MADEP has developed Method 1 Standards. TPH is a loosely defined parameter which provides an estimate of the total concentration of petroleum hydrocarbons in a sample. MADEP receives many questions from risk assessors and site managers regarding appropriate use of the Method 1 TPH Standard. This section is written to provide additional guidance on using the Method 1 Standard to evaluate releases of petroleum hydrocarbons.

*What is the meaning of the footnote associated with the Method 1 TPH Standard?*

The Method 1 Standards for TPH (contained in Tables 1-5 of Subpart I in the MCP) are marked with a footnote which reads:

Total Petroleum Hydrocarbon as measured using standard analytical methods or methods which provide toxicity-weighted concentrations, such as the MADEP TPH approach. This standard does not address and is not sufficient to evaluate specific chemicals which may be present in some petroleum products and which have promulgated MCP standards (such as benzene, toluene, ethylbenzene, xylenes and polycyclic aromatic hydrocarbons (PAHs)).

The Department has promulgated Method 1 standards for TPH to make it possible to more easily address, in a quantitative manner, the bulk of compounds in petroleum products which are difficult to identify and evaluate and which in the past, were largely ignored in risk assessments. In deciding to develop a TPH standard, the Department

recognized that there are difficulties associated with quantitatively evaluating the many chemicals present in petroleum products. The Department also recognized that there are risks associated with exposure to these compounds and they should not be ignored in the risk assessment. Thus, the TPH standard was developed to allow evaluation of the mass of compounds in petroleum products which typical analytical methods cannot quantify and for which good toxicity information does not exist.

Contrary to what its name suggests, the Method 1 TPH standard was developed without considering all of the compounds that may be present in petroleum products. In other words, the Method 1 TPH Standard is not, by itself, sufficient to evaluate the total number of compounds which may be present in a petroleum product. The TPH standard does not address and is not sufficient to evaluate all of the compounds which may be present in a petroleum product because in developing the TPH standard, the Department intentionally did not consider the toxicity of a number of compounds which are often present in petroleum products. Specifically, the TPH

standard does not incorporate common constituents of TPH which can be identified and quantified easily and constituents for which good toxicity information exists. In addition, the Department did not include additives that may be present in some petroleum products. Examples of compounds which are commonly present in petroleum products whose toxicities were not considered in developing the TPH standard are provided in the accompanying box. It should be clear that since the toxicity of these compounds was not considered in developing the TPH standard, these compounds must be evaluated separately from TPH in the risk assessment. In other words, comparison of site levels of TPH with the Method 1 standard for TPH does not eliminate the need to compare concentrations of other petroleum product constituents with their respective Method 1 standards.

**EXAMPLES OF  
COMPOUNDS NOT  
COVERED BY THE TPH  
STANDARD**

Benzene  
Toluene  
Ethylbenzene  
MTBE  
Xylenes  
Polycyclic Aromatic  
Hydrocarbons

*I want to be able to use the TPH standard, what analytical method(s) should I use to investigate the site?*

The MCP does not recommend specific analytical methods to be used for TPH (or for any other oil or hazardous material). Rather, the MCP relies on the use of professional judgement in selecting the analytical method most appropriate for a specific purpose. The first step is to determine the petroleum product(s) which may have been released at the site. MADEP recognizes that is often difficult, especially when the release occurred in the past. The site manager should use available historical records, site

observations, screening analyses, and any other relevant information in combination with professional judgement to identify the petroleum product(s) which may have been released at a site. Once the likely petroleum product(s) have been identified, the site manager can then select appropriate analytical methods.

It should be stressed that if one wants to use the Method 1 TPH standard, one will likely need more than just a TPH analysis to evaluate the petroleum hydrocarbons. Selecting an analytical method and selecting petroleum hydrocarbon compounds to analyze for should be done considering type of petroleum product that was released. If the site manager suspects that the petroleum product contained benzene, toluene, ethylbenzene, xylenes (BTEX) or PAHs, such compounds must be specifically analyzed for. For example, if the release of interest is gasoline from an old underground storage tank, the analyses should certainly include BTEX and TPH. The site manager should also consider analyzing for gasoline additives such as lead and MTBE. Site managers should refer to the MADEP *Policy for the Investigation, Assessment, and Remediation of Petroleum Releases* (1991) and the MADEP *Interim Final Petroleum Report: Development of Health-Based Alternative to the TPH Parameter* (1994) for information which may be helpful in identifying the chemicals which are may be associated with various petroleum products.

*When is development of a Method 2 standard needed?*

MADEP receives many questions regarding whether it is necessary to develop Method 2 Standards for specific petroleum hydrocarbons that a laboratory may report along with the TPH results. When performing TPH analyses, many laboratories also identify and quantify chemicals such as trimethylbenzenes, trichloropropane, 4-isopropyltoluene and isopropyl benzene. MADEP receives many questions regarding whether it is necessary to develop Method 2 standards for such chemicals or whether it is appropriate to simply compare site concentrations of TPH with the TPH standard. It is MADEP's view that if the mass of a chemical reported by a laboratory is included in the mass being reported in the TPH value, then the TPH standard is applicable and a separate Method 2 standard need not be developed.

However, recall that concentrations of BTEX and PAHs must be compared with their respective Method 1 standards, regardless of whether their mass is included in the mass being reported in the TPH analysis. This is because the toxicities of BTEX and PAHs were not considered by MADEP in the development of the TPH standard.

*If I have only TPH results, is that enough?*

In general, TPH alone will often not provide sufficient information to evaluate risks from petroleum hydrocarbons. Depending on the type of petroleum product released, it may

be necessary to analyze for the additional constituents whose toxicities were not considered in developing the Method 1 Standard for TPH (i.e. BTEX and PAHs).

## **5.10 CHARACTERIZING SAFETY RISKS**

The Method 1 risk characterization process does not specifically look at potential safety risks posed by the site, as safety is a concept which is difficult to distill down to a set of generic standards. As a result, the MCP requires that the risk of harm to safety be evaluated separately at all disposal sites: the same safety evaluation will occur whether a Method 1, Method 2 or Method 3 risk characterization is being performed. Section 4.0 of this guidance document discusses the MCP requirements (310 CMR 40.0960) for the evaluation of safety concerns. The characterization of site safety risk would be included as part of the overall documentation of the risk characterization.

## **5.11 DRAWING CONCLUSIONS FROM A METHOD 1 RISK CHARACTERIZATION**

The overall purpose of the risk characterization is to determine whether or not the site poses no significant risk of harm to health, safety, public welfare or the environment, and a clear statement of the results is required (310 CMR 40.0973(8)) in the documentation of the Method 1 risk characterization.

Sites where all exposure point concentrations fall below the applicable Method 1 standards (and where there is no risk to safety) require no further remedial response action to achieve a condition of No Significant Risk, and those sites may be eligible for a Class A or Class B Response Action Outcome (RAO) pursuant to Subpart J of the MCP. It is important to remember that achieving a condition of No Significant Risk is not the only requirement for an RAO: the regulations apropos Response Action Outcomes contain additional requirements for the elimination of continuing sources of oil or hazardous material (310 CMR 40.1003(5)), for implementing Activity and Use Limitations (310 CMR 40.1012) and for achieving background conditions (310 CMR 40.1020). The No Significant Risk standard should be thought of a minimum requirement, but it is not the only requirement governing site cleanup.

Figure 5-11

COMPARISON TO APPLICABLE MCP METHOD 1 SOIL STANDARDS					
EXPOSURE POINT	Oil or Hazardous Material	Exposure Point Concentration mg/kg	MCP Method 1 Soil Category and Applicable Standard		Check if Standard Exceeded
			Soil Category(ies)	Standard mg/kg	
#1 - Surface soil in yard at 10 Downing Street (see attached map)	Acenaphthene	50	S-1/GW-1	20	✓
			S-1/GW-3	1,000	
	Acetone	0.5	S-1 GW-1	3	
			S-1 GW-3	60	
	Aldrin	10	S-1/GW-1	0.03	✓
			S-1/GW-3	0.03	✓
#2 - Soil from 4' to 10', beneath pavement at 10 Downing Street (See attached map)	Acenaphthene	10	S-2/GW-1	20	
			S-2/GW-3	2,000	
	Acetone	ND	S-2/GW-1	3	
			S-2/GW-3	60	
	Aldrin	0.02	S-2/GW-1	0.04	
			S-2/GW-3	0.04	

COMPARISON TO APPLICABLE MCP METHOD 1 GROUNDWATER STANDARDS					
Exposure Point	Oil or Hazardous Material	Exposure Point Concentration µg/L	MCP Method 1 Groundwater Category and Applicable Standard		Check if Standard Exceeded
			Groundwater Category(ies)	Standard µg/L	
#1 - Private drinking water well at 10 Downing Street	Acenaphthene	35	GW-1	20	✓
			GW-3	2,000	
	Acetone	700	GW-1	3,000	
			GW-3	50,000	
	Aldrin	10	GW-1	0.5	✓
			GW-3	9	✓
#2 - Monitoring Well at downgradient property line at 10 Downing Street	Acenaphthene	10	GW-1	20	
			GW-3	2,000	
	Acetone	150	GW-1	3,000	
			GW-3	50,000	
	Aldrin	ND	GW-1	0.5	
			GW-3	9	

One important aspect of the MCP is that a distinction is made between *current* use, exposure and risk and *future* use, exposure and risk. One possible outcome of a Method 1 risk characterization is a demonstration that a condition of No Significant Risk has been achieved for current (but not future) conditions. A Class C Response Action Outcome is possible for such sites, as a demonstration that all substantial hazards have been eliminated (310 CMR 40.1050) is sufficient.

If one or more Exposure Point Concentrations exceed an applicable Method 1 standard, then a condition of No Significant Risk has not been achieved, and further response actions are required, although implementing a remedial response action is not the only course of action available. A more site-specific risk characterization approach (Method 2 or Method 3) may be employed to evaluate the site. For some sites where a Method 1 risk characterization has indicated that a condition of No Significant Risk has not been achieved, the site-specific approach might demonstrate that, in fact, a level of No Significant Risk does exist. (Of course the more detailed evaluation could also reach the same conclusions as the Method 1 assessment, but at significantly greater cost.) Guidance for conducting such risk characterization methods is contained in this document. Another option available is to conduct a remedial response action designed to reduce the concentrations of oil or hazardous material to levels below the Method 1 standards. A third approach would be to restrict future site use to those activities which would be consistent with a level of No Significant Risk. Under Method 1, the changes in site activities would have to be sufficient to change the soil or groundwater category and thus the applicable standards. Such limitation on site use would also require the application of Activity and Use Limitations (AULs). The response action chosen for a site may also be a combination of the options described above, as long as the result of the combined efforts is a site which poses no significant risk of harm to health, safety, public welfare and the environment.

## 5.12 ACTIVITY AND USE LIMITATIONS

The MCP requires the application of Activity and Use Limitations (AULs) whenever it is assumed that the future use of the property is not unrestricted. The AULs are used to inform future owners of the property of residual contamination and of potential uses of the property which could be inconsistent with the Response Action Outcome achieved for the site.

AULs are specifically not required at sites where the exposure point concentrations meet the soil category S-1 standards (310 CMR 40.0923(3)(b)2) or where the levels of oil or hazardous material are consistent with background. Such conditions are considered consistent with a level of No significant Risk for any use of a property.

Activity and Use Limitations are required whenever the condition of No Significant Risk has been achieved through implicit or explicit assumptions that the use of the property is such that exposure to the contaminated soil or groundwater is limited. For example, if the soil is categorized as S-2 because there is currently asphalt paving which prevents contact with the soil, then there is an implicit assumption that the asphalt covering will be maintained into the future. If soil is categorized as S-3 due to its depth (greater than 15 feet), then there is an implicit assumption that no excavation will take place on the property which will disturb those soils. If groundwater is not categorized as GW-2 because the land is currently vacant, there is an implicit assumption that no building will be constructed on the site which would result in reclassification of the groundwater. Such land use decisions may also be explicitly a part of a comprehensive remedial response action designed to eliminate or minimize potential exposures. All of these land use decisions must be conveyed to future owners of the property through Activity and Use Limitations. The regulations specific to AULs may be found in the MCP at 310 CMR 40.1012 and 40.1070.

Note that soils which are categorized as S-2 or S-3 based upon the current use of the property but which meet the S-1 standards for all the oil or hazardous material present do not require AULs as that property would be acceptable for unrestricted use.

The documentation which supports the risk characterization must clearly state the nature of the land or groundwater use restrictions which are incorporated into the risk characterization and describe the Activity and Use Limitations. The risk characterization results are not considered to be final until the all required Activity and Use Limitations are in place.

### 5.13 UNCERTAINTY ANALYSIS

The documentation of the Method 1 risk characterization should contain a discussion of the possible sources of uncertainty present in the site assessment and risk characterization process which could have an affect on the conclusions of the assessment. To the extent that it is known, the uncertainty discussion should describe whether the uncertainty is due to an incomplete knowledge of the site (e.g., the e.g., composite soil samples could mask the presence of a hot spot), incomplete data from the scientific literature or other information source (e.g., the GW-1 designation for a site may be based upon an Interim Wellhead Protection Area rather than a mapped Zone II, so the true impact on the public water supply well is unknown) or from the effects of natural, unquantified variability (e.g., natural fluctuation of the water table could result in a different depth to groundwater). The discussion should also indicate whether or not the uncertainty has a biased impact on the risk characterization results and, if possible, the magnitude of the effect.



## 6.0 METHOD 2 MODIFICATIONS

The Massachusetts Contingency Plan (MCP) describes three different methods for characterizing risk of harm to public health, public welfare and the environment at a disposal site. This chapter provides guidance on conducting a Method 2 Risk Characterization per 310 CMR 40.0980.

As described in Section 5.0 of this document, risk characterization Method 1 relies upon the use of promulgated, generic numerical standards for chemicals in groundwater and soil to characterize potential risk. The Method 1 Standards were developed by the Department using relatively conservative (health-protective) exposure assumptions to describe potential exposures which could occur to soil and groundwater. These defined sets of such assumptions (or "*exposure scenarios*") are considered to be conservative estimates of potential exposures at most sites. The details of the development of the Method 1 Standards are described in the *Background Documentation for the Development of the MCP Numerical Standards* (April 1994).

As described in Section 7.0 of this document, a Method 3 risk characterization employs site-specific exposure assumptions to characterize potential risks posed by contamination at a disposal site.

Thus, Method 1 and Method 3 represent the extremes on the generic/site-specific continuum.

Risk characterization Method 2 is a mixture of those two methods. Method 2 allows for limited modification of the generic Method 1 standards based upon site-specific information. The Method 2 approach provides some flexibility over the strict use of Method 1 Standards, but since the modifications allowed under Method 2 are focused on certain aspects of the standards, Method 2 results are not as site-specific as those obtained using Method 3. The Method 2 approach can be used to either supplement and/or modify the Method 1 standards in the following ways:

- Method 2 can be used to fill in data gaps by creating a Method 1 Standard where one does not presently exist. Method 1 standards were developed for 107 chemicals or groups of chemicals commonly reported at c.21E disposal sites. It is inevitable that many sites will have chemicals in the soil and groundwater for which Method 1 standards were not promulgated. Method 2 may be used to generate standards which are the equivalent of the MCP Method 1 values.
- Method 2 can also be used to incorporate site-specific fate and transport information to modify the existing Method 1 Standard. The Method 1 standards consider the potential

for chemicals to leach from the soil to groundwater, the potential for chemicals in groundwater to migrate to indoor air, and the potential for chemicals to discharge from the groundwater to surface water. These migration pathways may be examined under Method 2 using site-specific measurements and/or models to identify site-specific cleanup goals.

Note that the risk assessor may both develop a new standard for a chemical lacking a Method 1 standard and adjust the fate and transport aspects of that new standard to address site-specific conditions.

Whether the Method 2 standards are created *de novo* or represent modifications of existing Method 1 values, the process of risk characterization under Method 2 is similar to that of Method 1: site Exposure Point Concentrations are compared to the identified standards. If the site concentrations are equal to or less than the Method 2 standards then the risk assessor may conclude that a condition of No Significant Risk of harm to public health, welfare and the environment exists or has been achieved.

## 6.1 APPLICABILITY OF METHOD 2

The applicability of Method 2 is similar to that of Method 1, as noted at 310 CMR 40.0942(2), as both approaches rely upon the use of chemical-specific standards in soil and groundwater. The reader is referred to Sections 5.1 and 3.3 of this document which describe the applicability of Method 1 and the restrictions on the use of Method 2, respectively.

When determining whether Method 2 can be used to characterize the risk of harm to public health, welfare and the environment, the risk assessor should scrutinize both the inclusive and the exclusive criteria found at 310 CMR 40.0942. At certain sites the risk assessor will use a combination of Method 1 standards and standards derived using Method 2, at some sites the risk assessor may have to supplement the Method 2 risk characterization with some form of a Method 3 assessment, while at other sites Method 2 will not be an available option. The documentation of the risk characterization should affirm and document the applicability of Method 2 to the disposal site.

A Method 2 Risk Characterization should always be conducted in combination with a separate characterization of the risk of harm to safety posed by the contaminant conditions, as described in the MCP at 310 CMR 40.0960.

The detailed discussion in Section 5.0 of soil and groundwater categorization, identification of exposure points, determination of exposure point concentrations, and risk characterization apply to Method 2 as well as Method 1, and will not be repeated in this section. The

remainder of this section focuses on the differences between Method 1 and Method 2, which are related to the derivation and values of the standards used to characterize risk.

## 6.2 DERIVATION OF ADDITIONAL METHOD 1 STANDARDS

Method 1 Standards have been developed by MADEP for one hundred and six chemicals or groups of chemicals. These chemicals were targeted as being those most commonly encountered at disposal sites. When other chemicals are encountered at a disposal site, which are not included in this group, standards may be developed using Method 2. The procedures to be followed in developing groundwater standards are described in the MCP at 310 CMR 40.0983 (for groundwater) and 40.0984 (for soil).

The process and equations described under Method 2 mirror the methodology used to develop the MCP Method 1 standards in order that the numbers generated by the risk assessor in Method 2 be consistent and comparable to those developed by MADEP. In other words, the goal of this Method 2 approach is to develop a standard identical to what the Department would have derived if it had chosen to develop standards for that chemical. The *Background Documentation for the Development of the MCP Numerical Standards* (April 1994) provides additional detail and discussion of the methodology for developing groundwater and soil standards (Sections 4.0 and 5.0, respectively, in that document).

**Note that the equations and exposure assumptions to be used in deriving additional standards under Method 2 are contained in promulgated regulations (310 CMR 40.0983 and 310 CMR 40.0984) and cannot be changed by the risk assessor.**

When additional standards are developed by the risk assessor under Method 2 each step taken should be clearly identified and described. All sources utilized for the development of the standard should be referenced.

## 6.3 MODIFICATION OF EXISTING METHOD 1 STANDARDS

In developing the Method 1 soil and groundwater standards, MADEP made many health-protective assumptions about potential exposures and the movement of contaminants to ensure that the standards represent a level of No Significant Risk at virtually all disposal

are built into the categorization criteria. It is only for the GW-2 category that future changes in the use of the property could effect the groundwater category (i.e., constructing a building where there is presently no structure.)

All soil and groundwater must be categorized. There is no soil or groundwater which does not fit into one of the established categories.

## **5.7 IDENTIFICATION OF APPLICABLE METHOD 1 SOIL AND GROUNDWATER STANDARDS**

The categorization process summarized above is the basis for selecting the applicable soil and groundwater standards under Method 1. The regulations pertinent to the applicability of those standards are found at 310 CMR 40.0974 and 310 CMR 40.0975, for groundwater and soil, respectively.

The Department has published (MADEP, 1994) a detailed description of the development of the MCP Method 1 Standards.

The documentation which supports the risk characterization should include a list of the MCP Method 1 groundwater and soil standards determined to be applicable for the site (310 CMR 40.0973(5)).

### **5.7.1 Groundwater**

The Method 1 groundwater standards are listed at 310 CMR 40.0974(2), in Table 1 of Subpart I. A portion of that table is presented as Figure 5-2 for illustration purposes. The table of groundwater standards consists of five columns:

- the name of the oil or hazardous material,
- the CAS number of the oil or hazardous material,
- the GW-1 standard for the oil or hazardous material,
- the GW-2 standard for the oil or hazardous material, and
- the GW-3 standard for the oil or hazardous material.

As previously described, more than one groundwater category can apply to the groundwater at a site, and *all* groundwater is considered to be GW-3. Thus the standards listed in the last column (GW-3 Standard) of Table 1 (Figure 5-2) apply to the groundwater at all sites. In addition, the standards listed in column three (GW-1 Standard) and column four (GW-2 Standard) may also be applicable, depending upon site-specific factors. In the case when more than one category applies, for example, if the

groundwater at a site is GW-1, GW-2 and GW-3, then *all* the applicable standards must be considered, and the lowest applicable value would drive the risk characterization.

It is not true that GW-1 standards are always the lowest groundwater standards.

Because the groundwater categories look at markedly different exposure routes, any of the three categories may be the most sensitive, depending upon the chemical. In general, GW-3 is the most stringent category for pesticides and some metals, while the GW-2 standards may be lowest for some halogenated volatile chemicals.

FIGURE 5-2

310 CMR 40.0974(2)

TABLE 1

MCP Method 1 GROUNDWATER STANDARDS  
APPLICABLE IN AREAS WHERE THE GROUNDWATER  
IS CONSIDERED TO BE ONE OR MORE OF THE  
FOLLOWING CATEGORIES PER 310 CMR 40.0932

Oil and/or hazardous Material	CAS Number	GW-1 Standard	GW-2 Standard	GW-3 Standard
		µg/liter (ppb)	µg/liter (ppb)	µg/liter (ppb)
ACENAPHTHENE	83329	20	NA	2,000
ACENAPHTHYLENE	208968	300	NA	2,000
ACETONE	67641	3,000	50,000	50,000
ALDRIN	309002	0.5	0.5	9
ANTHRACENE	120127	600	NA	600

This table is presented as an example of the *format* in the regulations. Consult the actual table in the regulations for current standards.

### 5.7.2. Soil

The Method 1 soil standards are listed at 310 CMR 40.0975(6) in the MCP. The soil standards are organized in three tables (Subpart I Tables 2, 3 and 4), and a portion of each is presented for illustration purposes in Figures 5-3, 5-4 and 5-5, respectively. Each table is specific to a single soil category: Table 2 contains all the MCP Method 1 Category S-1 standards, Table 3 contains all the Method 1 Category S-2 standards, and Table 4 contains all the Method 1 Category S-3 standards. Each table is made up of 5 columns:

- the name of the oil or hazardous material,
- the CAS number of the oil or hazardous material,
- the soil standard for soil overlying a GW-1 aquifer,
- the soil standard for soil overlying a GW-2 aquifer,
- the soil standard for soil overlying a GW-3 aquifer.

Figure 5-3

310 CMR 40.0975(6)(a)				
TABLE 2				
MCP Method 1: SOIL CATEGORY S-1 STANDARDS				
APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:				
Oil and/or hazardous Material	CAS Number	S-1 SOIL & GW-1	S-1 SOIL & GW-2	S-1 SOIL & GW-3
		µg/g (ppm)	µg/g (ppm)	µg/g (ppm)
ACENAPHTHENE	83329	20	1,000	1,000
ACENAPHTHYLENE	208968	100	100	100
ACETONE	67641	3	60	60
ALDRIN	309002	0.03	0.03	0.03
ANTHRACENE	120127	1,000	1,000	1,000
This table is presented as an example of the <i>format</i> in the regulations. Consult the actual table in the regulations for current standards.				

The soil standards were derived in consideration of potential direct contact exposures (incidental soil ingestion and dermal contact) and considering the potential for the oil or hazardous material to leach from the soil and contaminate the underlying groundwater. Thus the allowable level of a chemical in soil depends, in part, upon the allowable level of the chemical in the groundwater. If the groundwater at the site is determined to be in more than one groundwater category (e.g., both GW-2 and GW-3) then more than one

soil standard will apply (e.g., both S-1/GW-2 and S-1/GW-3) and the lowest of the applicable standards will drive the risk characterization.

Figure 5-4

310 CMR 40.0975(6)(b)				
TABLE 3				
MCP Method 1: SOIL CATEGORY S-2 STANDARDS				
APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:				
Oil and/or hazardous Material	CAS Number	S-2 SOIL & GW-1	S-2 SOIL & GW-2	S-2 SOIL & GW-3
		µg/g (ppm)	µg/g (ppm)	µg/g (ppm)
ACENAPHTHENE	83329	20	2,500	2,000
ACENAPHTHYLENE	208968	100	2,500	800
ACETONE	67641	3	60	60
ALDRIN	309002	0.04	0.04	0.04
ANTHRACENE	120127	1,000	2,500	1,000
This table is presented as an example of the <i>format</i> in the regulations. Consult the actual table in the regulations for current standards.				

Figure 5-5

310 CMR 40.0975(6)(c)				
TABLE 4				
MCP Method 1: SOIL CATEGORY S-3 STANDARDS				
APPLICABLE TO SOIL WHERE THE COMBINATION OF SOIL & GROUNDWATER CATEGORIES ARE:				
Oil and/or hazardous Material	CAS Number	S-3 SOIL & GW-1	S-3 SOIL & GW-2	S-3 SOIL & GW-3
		µg/g (ppm)	µg/g (ppm)	µg/g (ppm)
ACENAPHTHENE	83329	20	5,000	2,000
ACENAPHTHYLENE	208968	100	2,500	800
ACETONE	67641	3	60	60
ALDRIN	309002	0.1	0.1	0.1
ANTHRACENE	120127	1,000	5,000	1,000
This table is presented as an example of the <i>format</i> in the regulations. Consult the actual table in the regulations for current standards.				

Interestingly, the leaching-to-groundwater pathway is often more sensitive (produces a lower allowable soil concentration) than the direct contact exposure pathway. As a result, many of the standards for S-1, S-2 and S-3 soil overlying a particular groundwater category will be the same value: for example the S-1/GW-1, S-2/GW-1 and S-3/GW-1 standards for acetone in the tables above are all 3  $\mu\text{g/g}$ . Thus, while one would expect the allowable acetone soil concentration to increase as the soil category increases (S-1 soil to S-3 soil, or high to low exposure potential), this does not occur.

## 5.8 IDENTIFICATION OF EXPOSURE POINTS AND EXPOSURE POINT CONCENTRATIONS (Including Hot Spots)

The regulations which address the identification of exposure points and the development of exposure point concentrations for Method 1 risk characterizations are found at 310 CMR 40.0973(3) and (4). More general discussion of these terms appears at 310 CMR 40.0924 and 40.0926.

### 5.8.1. Groundwater

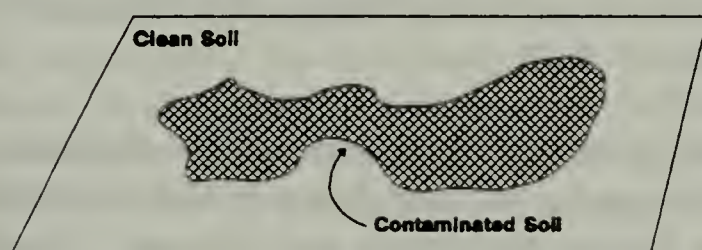
For groundwater, the MCP defines the exposure point to be used for a Method 1 risk characterization as *"...the wellhead and/or nearest tap of a well screened within the horizontal and vertical distribution of the oil or hazardous material in the groundwater. Existing water supply wells and monitoring wells shall be considered current or potential Exposure Points..."* (310 CMR 40.0973(3)(a)). Thus each well located within the contaminated area is considered either a current or future exposure point.

The exposure point concentrations for groundwater are thus easily identified as the concentrations reported from each water supply or monitoring well, as described in 310 CMR 40.0973(4)(b). Limited averaging over time of these reported concentrations would be consistent with the statement at 310 CMR 40.0926 that exposure point concentrations shall be arithmetic averages providing a conservative estimate of the concentration at the exposure point, although averaging of data across wells (across exposure points) is not acceptable for Method 1. The quality of data collected in the past and trends in the data should be assessed to determine whether a temporal average is appropriate to yield a conservative estimate. There are, of course, situations when the maximum concentration reported (or an upper percentile) is appropriate, including the evaluation of acute exposures, the evaluation of chemicals associated with lethal or severe health effects, evaluations performed with insufficient data, or conservative screening assessments.

## 5.8.2 Soil

In the MCP the exposure points for soil are defined by *"the vertical and horizontal distribution of the material in soil in combination with the soil category(ies) determined to be applicable"* (310 CMR 40.0973(3)(b)). Thus, in order to identify the soil exposure points for a Method 1 risk characterization the investigator must know the extent of contamination and how the soil would be categorized at the site. Figures 5-5 through 5-10 describe situations which may arise when identifying soil exposure points.

Figure 5-6



The Exposure Point Would Include Only The Contaminated Soil

First, Method 1 soil Exposure Points encompass only continuous areas of contaminated soil and do not include clean soil. Thus, the boundary of an Exposure Point is no larger than the extent of the soil contamination at the site. Figure 5-6 illustrates that only the area of contamination would be considered the soil Exposure Point.

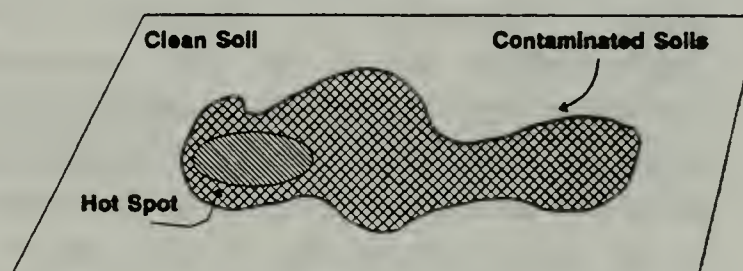
Second, hot spots are specifically identified (310 CMR 40.0924(2)) as distinct exposure points. The identification of a *"hot spot"* is discussed in more detail in Section 2.2.3 of this document, but is defined within the MCP as a discrete area with substantially higher contamination relative to the surrounding area. Thus, if a hot spot exists with a larger area of contamination, there would be at least two Exposure Points identified: the hot spot and the area of more generalized contamination. Figure 5-7 illustrates a hot spot as a distinct exposure point.

Third, if the area of contaminated soil is not contiguous, then the discrete areas of contaminated soil which exist at the site are treated as a separate Exposure Point. Figure 5-8 illustrates this point.

Finally, if the boundary of a soil category bisects the contaminated area, then the soil which falls within each soil category is treated as separate Exposure Points. Figure 5-9 illustrates how this may occur.

It is also important to remember that the exposure points exist in three dimensions. Figures 5-6 through 5-9 present exposure points in two dimensions for clarity, but there is a depth component

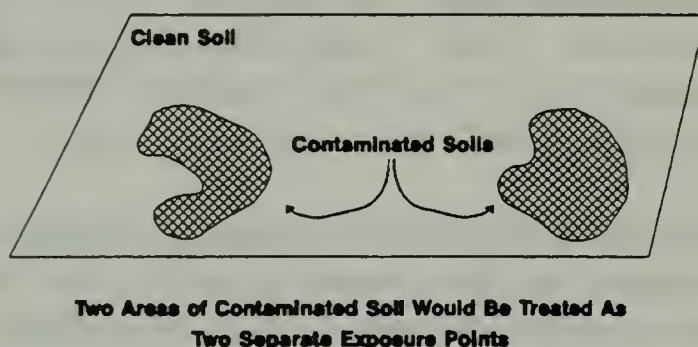
Figure 5-7



A Hot Spot Within An Area Of Contaminated Soil Is Treated As A Distinct Exposure Point

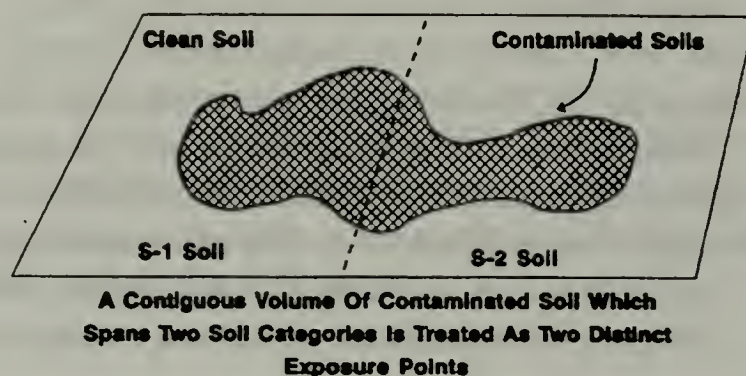
as well, which is why the term "volume" is used in the MCP in the discussion of Method 1 exposure points (310 CMR 40.0973(3)(b)). Thus, a volume of contaminated soil five feet below ground would be considered a Method 1 Exposure Point, and that Exposure Point would not include the uncontaminated soil on the surface (See Figure 5-10). Multiple soil categories, hot spots and disconnected contamination would be considered in the same manner in three dimensions as they were described above.

**Figure 5-8**



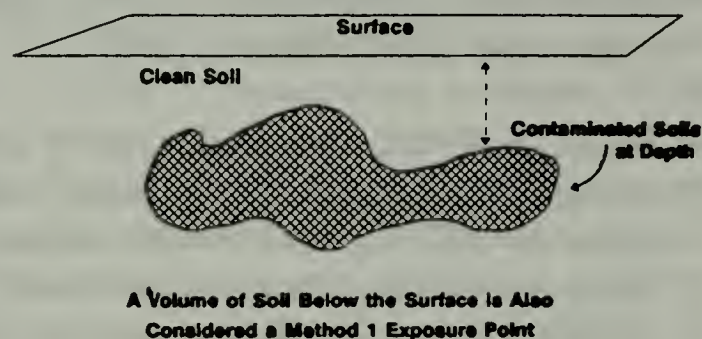
The exposure point concentrations for soil are representative concentrations for the oil or hazardous material within each exposure point. Typically the Exposure Point Concentration would be the arithmetic average of the contaminant concentration, although consideration should be given to using the maximum concentration reported or an upper percentile of the range of concentrations reported when the site data may not be adequate, when evaluating acute exposures, when evaluating chemicals associated with lethal or severe health effects or when performing screening assessments (310 CMR 40.0926(3)). Since the Method 1 exposure point is defined such that it excludes uncontaminated soil, analytical results

**Figure 5-9**



Soil at depth is considered an Exposure Point under Method 1 due to the potential for future excavation and contact. Since such potential future exposures are part of the basic premise of Method 1 (310 CMR 40.0972), the risk assessor cannot eliminate this exposure pathway (determine that such exposure would never occur, and that the soil at depth does not constitute an Exposure Point) when using Method 1 to characterize risk, although such site-specific risk assessment may be appropriate under a Method 3 assessment.

**Figure 5-10**



from "clean" areas of the site should not be incorporated into the exposure point concentration.

## 5.9 CHARACTERIZING RISK UNDER METHOD 1

Having identified the Method 1 standards applicable to the site (Section 5.7) and the site Exposure Points and Exposure Point Concentrations (Section 5.8), the risk characterization is simply the comparison of the exposure point concentrations to the applicable Method 1 standards. As described in the MCP (310 CMR 40.0973(7)), *"a condition of no significant risk of harm to health, public welfare or the environment exists if no Exposure Point Concentration is greater than the applicable MCP Method 1 Soil or Groundwater Standard"*. The report which documents the risk characterization should include tables ordered by environmental medium and exposure point comparing the exposure point concentrations to the applicable MCP Method 1 standards. An example of such a table is presented in Figure 5-11.

### 5.9.1 Characterizing Risks Using TPH Data

#### Using the Method 1 Standard for Total Petroleum Hydrocarbon

Total Petroleum Hydrocarbon, or TPH, is one of the one hundred and seven chemicals (or groups of chemicals) for which MADEP has developed Method 1 Standards. TPH is a loosely defined parameter which provides an estimate of the total concentration of petroleum hydrocarbons in a sample. MADEP receives many questions from risk assessors and site managers regarding appropriate use of the Method 1 TPH Standard. This section is written to provide additional guidance on using the Method 1 Standard to evaluate releases of petroleum hydrocarbons.

*What is the meaning of the footnote associated with the Method 1 TPH Standard?*

The Method 1 Standards for TPH (contained in Tables 1-5 of Subpart I in the MCP) are marked with a footnote which reads:

Total Petroleum Hydrocarbon as measured using standard analytical methods or methods which provide toxicity-weighted concentrations, such as the MADEP TPH approach. This standard does not address and is not sufficient to evaluate specific chemicals which may be present in some petroleum products and which have promulgated MCP standards (such as benzene, toluene, ethylbenzene, xylenes and polycyclic aromatic hydrocarbons (PAHs)).

The Department has promulgated Method 1 standards for TPH to make it possible to more easily address, in a quantitative manner, the bulk of compounds in petroleum products which are difficult to identify and evaluate and which in the past, were largely ignored in risk assessments. In deciding to develop a TPH standard, the Department

recognized that there are difficulties associated with quantitatively evaluating the many chemicals present in petroleum products. The Department also recognized that there are risks associated with exposure to these compounds and they should not be ignored in the risk assessment. Thus, the TPH standard was developed to allow evaluation of the mass of compounds in petroleum products which typical analytical methods cannot quantify and for which good toxicity information does not exist.

Contrary to what its name suggests, the Method 1 TPH standard was developed without considering all of the compounds that may be present in petroleum products. In other words, the Method 1 TPH Standard is not, by itself, sufficient to evaluate the total number of compounds which may be present in a petroleum product. The TPH standard does not address and is not sufficient to evaluate all of the compounds which may be present in a petroleum product because in developing the TPH standard, the Department intentionally did not consider the toxicity of a number of compounds which are often present in petroleum products. Specifically, the TPH

standard does not incorporate common constituents of TPH which can be identified and quantified easily and constituents for which good toxicity information exists. In addition, the Department did not include additives that may be present in some petroleum products. Examples of compounds which are commonly present in petroleum products whose toxicities were not considered in developing the TPH standard are provided in the accompanying box. It should be clear that since the toxicity of these compounds was not considered in developing the TPH standard, these compounds must be evaluated separately from TPH in the risk assessment. In other words, comparison of site levels of TPH with the Method 1 standard for TPH does not eliminate the need to compare concentrations of other petroleum product constituents with their respective Method 1 standards.

**EXAMPLES OF  
COMPOUNDS NOT  
COVERED BY THE TPH  
STANDARD**

Benzene  
Toluene  
Ethylbenzene  
MTBE  
Xylenes  
Polycyclic Aromatic  
Hydrocarbons

*I want to be able to use the TPH standard, what analytical method(s) should I use to investigate the site?*

The MCP does not recommend specific analytical methods to be used for TPH (or for any other oil or hazardous material). Rather, the MCP relies on the use of professional judgement in selecting the analytical method most appropriate for a specific purpose. The first step is to determine the petroleum product(s) which may have been released at the site. MADEP recognizes that is often difficult, especially when the release occurred in the past. The site manager should use available historical records, site

observations, screening analyses, and any other relevant information in combination with professional judgement to identify the petroleum product(s) which may have been released at a site. Once the likely petroleum product(s) have been identified, the site manager can then select appropriate analytical methods.

It should be stressed that if one wants to use the Method 1 TPH standard, one will likely need more than just a TPH analysis to evaluate the petroleum hydrocarbons. Selecting an analytical method and selecting petroleum hydrocarbon compounds to analyze for should be done considering type of petroleum product that was released. If the site manager suspects that the petroleum product contained benzene, toluene, ethylbenzene, xylenes (BTEX) or PAHs, such compounds must be specifically analyzed for. For example, if the release of interest is gasoline from an old underground storage tank, the analyses should certainly include BTEX and TPH. The site manager should also consider analyzing for gasoline additives such as lead and MTBE. Site managers should refer to the MADEP *Policy for the Investigation, Assessment, and Remediation of Petroleum Releases* (1991) and the MADEP *Interim Final Petroleum Report: Development of Health-Based Alternative to the TPH Parameter* (1994) for information which may be helpful in identifying the chemicals which are may be associated with various petroleum products.

*When is development of a Method 2 standard needed?*

MADEP receives many questions regarding whether it is necessary to develop Method 2 Standards for specific petroleum hydrocarbons that a laboratory may report along with the TPH results. When performing TPH analyses, many laboratories also identify and quantify chemicals such as trimethylbenzenes, trichloropropane, 4-isopropyltoluene and isopropyl benzene. MADEP receives many questions regarding whether it is necessary to develop Method 2 standards for such chemicals or whether it is appropriate to simply compare site concentrations of TPH with the TPH standard. It is MADEP's view that if the mass of a chemical reported by a laboratory is included in the mass being reported in the TPH value, then the TPH standard is applicable and a separate Method 2 standard need not be developed.

However, recall that concentrations of BTEX and PAHs must be compared with their respective Method 1 standards, regardless of whether their mass is included in the mass being reported in the TPH analysis. This is because the toxicities of BTEX and PAHs were not considered by MADEP in the development of the TPH standard.

*If I have only TPH results, is that enough?*

In general, TPH alone will often not provide sufficient information to evaluate risks from petroleum hydrocarbons. Depending on the type of petroleum product released, it may

be necessary to analyze for the additional constituents whose toxicities were not considered in developing the Method 1 Standard for TPH (i.e. BTEX and PAHs).

## **5.10 CHARACTERIZING SAFETY RISKS**

The Method 1 risk characterization process does not specifically look at potential safety risks posed by the site, as safety is a concept which is difficult to distill down to a set of generic standards. As a result, the MCP requires that the risk of harm to safety be evaluated separately at all disposal sites: the same safety evaluation will occur whether a Method 1, Method 2 or Method 3 risk characterization is being performed. Section 4.0 of this guidance document discusses the MCP requirements (310 CMR 40.0960) for the evaluation of safety concerns. The characterization of site safety risk would be included as part of the overall documentation of the risk characterization.

## **5.11 DRAWING CONCLUSIONS FROM A METHOD 1 RISK CHARACTERIZATION**

The overall purpose of the risk characterization is to determine whether or not the site poses no significant risk of harm to health, safety, public welfare or the environment, and a clear statement of the results is required (310 CMR 40.0973(8)) in the documentation of the Method 1 risk characterization.

Sites where all exposure point concentrations fall below the applicable Method 1 standards (and where there is no risk to safety) require no further remedial response action to achieve a condition of No Significant Risk, and those sites may be eligible for a Class A or Class B Response Action Outcome (RAO) pursuant to Subpart J of the MCP. It is important to remember that achieving a condition of No Significant Risk is not the only requirement for an RAO: the regulations apropos Response Action Outcomes contain additional requirements for the elimination of continuing sources of oil or hazardous material (310 CMR 40.1003(5)), for implementing Activity and Use Limitations (310 CMR 40.1012) and for achieving background conditions (310 CMR 40.1020). The No Significant Risk standard should be thought of a minimum requirement, but it is not the only requirement governing site cleanup.

Figure 5-11

COMPARISON TO APPLICABLE MCP METHOD 1 SOIL STANDARDS					
EXPOSURE POINT	Oil or Hazardous Material	Exposure Point Concentration mg/kg	MCP Method 1 Soil Category and Applicable Standard		Check if Standard Exceeded
			Soil Category(ies)	Standard mg/kg	
#1 - Surface soil in yard at 10 Downing Street (see attached map)	Acenaphthene	50	S-1/GW-1	20	✓
			S-1/GW-3	1,000	
	Acetone	0.5	S-1 GW-1	3	
			S-1 GW-3	60	
	Aldrin	10	S-1/GW-1	0.03	✓
			S-1/GW-3	0.03	
#2 - Soil from 4' to 10', beneath pavement at 10 Downing Street (See attached map)	Acenaphthene	10	S-2/GW-1	20	
			S-2/GW-3	2,000	
	Acetone	ND	S-2/GW-1	3	
			S-2/GW-3	60	
	Aldrin	0.02	S-2/GW-1	0.04	
			S-2/GW-3	0.04	

COMPARISON TO APPLICABLE MCP METHOD 1 GROUNDWATER STANDARDS					
Exposure Point	Oil or Hazardous Material	Exposure Point Concentration µg/L	MCP Method 1 Groundwater Category and Applicable Standard		Check if Standard Exceeded
			Groundwater Category(ies)	Standard µg/L	
#1 - Private drinking water well at 10 Downing Street	Acenaphthene	35	GW-1	20	✓
			GW-3	2,000	
	Acetone	700	GW-1	3,000	
			GW-3	50,000	
	Aldrin	10	GW-1	0.5	✓
			GW-3	9	
#2 - Monitoring Well at downgradient property line at 10 Downing Street	Acenaphthene	10	GW-1	20	
			GW-3	2,000	
	Acetone	150	GW-1	3,000	
			GW-3	50,000	
	Aldrin	ND	GW-1	0.5	
			GW-3	9	

One important aspect of the MCP is that a distinction is made between *current* use, exposure and risk and *future* use, exposure and risk. One possible outcome of a Method 1 risk characterization is a demonstration that a condition of No Significant Risk has been achieved for current (but not future) conditions. A Class C Response Action Outcome is possible for such sites, as a demonstration that all substantial hazards have been eliminated (310 CMR 40.1050) is sufficient.

If one or more Exposure Point Concentrations exceed an applicable Method 1 standard, then a condition of No Significant Risk has not been achieved, and further response actions are required, although implementing a remedial response action is not the only course of action available. A more site-specific risk characterization approach (Method 2 or Method 3) may be employed to evaluate the site. For some sites where a Method 1 risk characterization has indicated that a condition of No Significant Risk has not been achieved, the site-specific approach might demonstrate that, in fact, a level of No Significant Risk does exist. (Of course the more detailed evaluation could also reach the same conclusions as the Method 1 assessment, but at significantly greater cost.) Guidance for conducting such risk characterization methods is contained in this document. Another option available is to conduct a remedial response action designed to reduce the concentrations of oil or hazardous material to levels below the Method 1 standards. A third approach would be to restrict future site use to those activities which would be consistent with a level of No Significant Risk. Under Method 1, the changes in site activities would have to be sufficient to change the soil or groundwater category and thus the applicable standards. Such limitation on site use would also require the application of Activity and Use Limitations (AULs). The response action chosen for a site may also be a combination of the options described above, as long as the result of the combined efforts is a site which poses no significant risk of harm to health, safety, public welfare and the environment.

## 5.12 ACTIVITY AND USE LIMITATIONS

The MCP requires the application of Activity and Use Limitations (AULs) whenever it is assumed that the future use of the property is not unrestricted. The AULs are used to inform future owners of the property of residual contamination and of potential uses of the property which could be inconsistent with the Response Action Outcome achieved for the site.

AULs are specifically not required at sites where the exposure point concentrations meet the soil category S-1 standards (310 CMR 40.0923(3)(b)2) or where the levels of oil or hazardous material are consistent with background. Such conditions are considered consistent with a level of No significant Risk for any use of a property.

Activity and Use Limitations are required whenever the condition of No Significant Risk has been achieved through implicit or explicit assumptions that the use of the property is such that exposure to the contaminated soil or groundwater is limited. For example, if the soil is categorized as S-2 because there is currently asphalt paving which prevents contact with the soil, then there is an implicit assumption that the asphalt covering will be maintained into the future. If soil is categorized as S-3 due to its depth (greater than 15 feet), then there is an implicit assumption that no excavation will take place on the property which will disturb those soils. If groundwater is not categorized as GW-2 because the land is currently vacant, there is an implicit assumption that no building will be constructed on the site which would result in reclassification of the groundwater. Such land use decisions may also be explicitly a part of a comprehensive remedial response action designed to eliminate or minimize potential exposures. All of these land use decisions must be conveyed to future owners of the property through Activity and Use Limitations. The regulations specific to AULs may be found in the MCP at 310 CMR 40.1012 and 40.1070.

Note that soils which are categorized as S-2 or S-3 based upon the current use of the property but which meet the S-1 standards for all the oil or hazardous material present do not require AULs as that property would be acceptable for unrestricted use.

The documentation which supports the risk characterization must clearly state the nature of the land or groundwater use restrictions which are incorporated into the risk characterization and describe the Activity and Use Limitations. The risk characterization results are not considered to be final until the all required Activity and Use Limitations are in place.

### 5.13 UNCERTAINTY ANALYSIS

The documentation of the Method 1 risk characterization should contain a discussion of the possible sources of uncertainty present in the site assessment and risk characterization process which could have an affect on the conclusions of the assessment. To the extent that it is known, the uncertainty discussion should describe whether the uncertainty is due to an incomplete knowledge of the site (e.g., the e.g., composite soil samples could mask the presence of a hot spot), incomplete data from the scientific literature or other information source (e.g., the GW-1 designation for a site may be based upon an Interim Wellhead Protection Area rather than a mapped Zone II, so the true impact on the public water supply well is unknown) or from the effects of natural, unquantified variability (e.g., natural fluctuation of the water table could result in a different depth to groundwater). The discussion should also indicate whether or not the uncertainty has a biased impact on the risk characterization results and, if possible, the magnitude of the effect.



## 6.0 METHOD 2 MODIFICATIONS

The Massachusetts Contingency Plan (MCP) describes three different methods for characterizing risk of harm to public health, public welfare and the environment at a disposal site. This chapter provides guidance on conducting a Method 2 Risk Characterization per 310 CMR 40.0980.

As described in Section 5.0 of this document, risk characterization Method 1 relies upon the use of promulgated, generic numerical standards for chemicals in groundwater and soil to characterize potential risk. The Method 1 Standards were developed by the Department using relatively conservative (health-protective) exposure assumptions to describe potential exposures which could occur to soil and groundwater. These defined sets of such assumptions (or "*exposure scenarios*") are considered to be conservative estimates of potential exposures at most sites. The details of the development of the Method 1 Standards are described in the *Background Documentation for the Development of the MCP Numerical Standards* (April 1994).

As described in Section 7.0 of this document, a Method 3 risk characterization employs site-specific exposure assumptions to characterize potential risks posed by contamination at a disposal site.

Thus, Method 1 and Method 3 represent the extremes on the generic/site-specific continuum.

Risk characterization Method 2 is a mixture of those two methods. Method 2 allows for limited modification of the generic Method 1 standards based upon site-specific information. The Method 2 approach provides some flexibility over the strict use of Method 1 Standards, but since the modifications allowed under Method 2 are focused on certain aspects of the standards, Method 2 results are not as site-specific as those obtained using Method 3. The Method 2 approach can be used to either supplement and/or modify the Method 1 standards in the following ways:

- Method 2 can be used to fill in data gaps by creating a Method 1 Standard where one does not presently exist. Method 1 standards were developed for 107 chemicals or groups of chemicals commonly reported at c.21E disposal sites. It is inevitable that many sites will have chemicals in the soil and groundwater for which Method 1 standards were not promulgated. Method 2 may be used to generate standards which are the equivalent of the MCP Method 1 values.
- Method 2 can also be used to incorporate site-specific fate and transport information to modify the existing Method 1 Standard. The Method 1 standards consider the potential

for chemicals to leach from the soil to groundwater, the potential for chemicals in groundwater to migrate to indoor air, and the potential for chemicals to discharge from the groundwater to surface water. These migration pathways may be examined under Method 2 using site-specific measurements and/or models to identify site-specific cleanup goals.

Note that the risk assessor may both develop a new standard for a chemical lacking a Method 1 standard and adjust the fate and transport aspects of that new standard to address site-specific conditions.

Whether the Method 2 standards are created *de novo* or represent modifications of existing Method 1 values, the process of risk characterization under Method 2 is similar to that of Method 1: site Exposure Point Concentrations are compared to the identified standards. If the site concentrations are equal to or less than the Method 2 standards then the risk assessor may conclude that a condition of No Significant Risk of harm to public health, welfare and the environment exists or has been achieved.

## 6.1 APPLICABILITY OF METHOD 2

The applicability of Method 2 is similar to that of Method 1, as noted at 310 CMR 40.0942(2), as both approaches rely upon the use of chemical-specific standards in soil and groundwater. The reader is referred to Sections 5.1 and 3.3 of this document which describe the applicability of Method 1 and the restrictions on the use of Method 2, respectively.

When determining whether Method 2 can be used to characterize the risk of harm to public health, welfare and the environment, the risk assessor should scrutinize both the inclusive and the exclusive criteria found at 310 CMR 40.0942. At certain sites the risk assessor will use a combination of Method 1 standards and standards derived using Method 2, at some sites the risk assessor may have to supplement the Method 2 risk characterization with some form of a Method 3 assessment, while at other sites Method 2 will not be an available option. The documentation of the risk characterization should affirm and document the applicability of Method 2 to the disposal site.

A Method 2 Risk Characterization should always be conducted in combination with a separate characterization of the risk of harm to safety posed by the contaminant conditions, as described in the MCP at 310 CMR 40.0960.

The detailed discussion in Section 5.0 of soil and groundwater categorization, identification of exposure points, determination of exposure point concentrations, and risk characterization apply to Method 2 as well as Method 1, and will not be repeated in this section. The

remainder of this section focuses on the differences between Method 1 and Method 2, which are related to the derivation and values of the standards used to characterize risk.

## 6.2 DERIVATION OF ADDITIONAL METHOD 1 STANDARDS

Method 1 Standards have been developed by MADEP for one hundred and six chemicals or groups of chemicals. These chemicals were targeted as being those most commonly encountered at disposal sites. When other chemicals are encountered at a disposal site, which are not included in this group, standards may be developed using Method 2. The procedures to be followed in developing groundwater standards are described in the MCP at 310 CMR 40.0983 (for groundwater) and 40.0984 (for soil).

The process and equations described under Method 2 mirror the methodology used to develop the MCP Method 1 standards in order that the numbers generated by the risk assessor in Method 2 be consistent and comparable to those developed by MADEP. In other words, the goal of this Method 2 approach is to develop a standard identical to what the Department would have derived if it had chosen to develop standards for that chemical. The *Background Documentation for the Development of the MCP Numerical Standards* (April 1994) provides additional detail and discussion of the methodology for developing groundwater and soil standards (Sections 4.0 and 5.0, respectively, in that document).

**Note that the equations and exposure assumptions to be used in deriving additional standards under Method 2 are contained in promulgated regulations (310 CMR 40.0983 and 310 CMR 40.0984) and cannot be changed by the risk assessor.**

When additional standards are developed by the risk assessor under Method 2 each step taken should be clearly identified and described. All sources utilized for the development of the standard should be referenced.

## 6.3 MODIFICATION OF EXISTING METHOD 1 STANDARDS

In developing the Method 1 soil and groundwater standards, MADEP made many health-protective assumptions about potential exposures and the movement of contaminants to ensure that the standards represent a level of No Significant Risk at virtually all disposal

sites to which they are applicable. For any given disposal site, however, investigations may reveal that the fate and transport models employed to develop the Method 1 standards overestimate (or underestimate) potential risks. Under Method 2, site-specific information may be used to demonstrate and document that a concentration of oil or hazardous material which is different than an applicable Method 1 standard poses No Significant Risk. Such a concentration would be used in the risk characterization process as the Method 2 standard.

Examples of such Method 2 demonstrations include:

- The use of site-specific leaching models to document that residual soil levels will not result in an exceedance of an applicable groundwater standard;
- The use of site-specific volatilization models to document that groundwater contaminants will not result in unacceptable indoor air concentrations;
- The use of site-specific migration models to demonstrate that the groundwater will not pose a significant risk when it discharges to surface water.

Note that there are some Method 1 standards which cannot be modified under Method 2 (see 310 CMR 40.0982(1) and (2)). For example, groundwater protected as a current or potential source of drinking water must meet the promulgated GW-1 standards listed in MCP Table 1 (310 CMR 40.0974(2)). Similarly, while some site-specific information may be used to adjust the leaching-component of the soil standards, the results cannot exceed soil standards based upon direct contact exposures. These soil standards are listed in MCP Table 5 (310 CMR 40.0985(6)).

The fate and transport modifications to the Method 1 standards which are allowed under a Method 2 risk characterization rely heavily upon models used to predict environmental concentrations of oil or hazardous material, although direct environmental monitoring may also be employed.

### 6.3.1 General Considerations When Using Predictive Models

Predictive modeling used in Method 2 to modify Method 1 standards is one prominent example of how such models may be used under the MCP. The discussion which follows is applicable to all uses of fate and transport models<sup>1</sup>.

While direct measurements of environmental concentrations are preferred, Predictive Modeling is often a necessary or desirable component of the risk characterization process, providing a means to:

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<sup>1</sup> The use of predictive models is not permissible under Method 1, except to evaluate future site conditions. Predictive models may be used under Method 3 as needed and appropriate to obtain estimates of current and/or future Exposure Point Concentrations, as discussed in Section 7.3.4.5 of this document.

- adjust the promulgated Method 1 standards based upon site-specific fate and transport information; and/or
- characterize risks at a site that may be manifested at a future point in time or space, due to the migration, partitioning, or transformation of oil and hazardous material; and/or
- interpret, characterize, or confirm current risks at a site, from migration and/or exposure pathways that are difficult or impossible to accurately measure or quantify.

Although Predictive Modeling has become an integral part of the site assessment and risk characterization process, there has been little standardization, or indeed validation, of modeling procedures and techniques. This situation has been further exacerbated by the explosive growth in commercially available software, capable of executing increasingly more complex modeling applications, on increasingly more powerful computers.

For this reason, risk assessors should exercise appropriate caution in the evaluation, utilization, and interpretation of modeling results. Further, the risk assessor must justify and document the use of a predictive model as part of a Method 2 Risk Characterization.

#### **6.3.1.1 Types of Predictive Models**

Predictive Models are mathematical approximations of processes that occur at a disposal site. These models attempt to evaluate the migration of oil and hazardous material released at a site by the mathematical simulation of physical, chemical, and/or biological processes.

Most models used for this purpose are classified as either "analytical" or "numerical" models:

- **Analytical Models** are relatively simple mathematical relationships or algorithms, with solutions obtained through hand calculation or on a personal computer. Generally, the use of analytical models requires a series of simplifying assumptions and conditions.
- **Numerical Models** are more complex mathematical relationships, with solutions obtained through a numerical analysis using a computer program. Numerical models allow for the evaluation of more complex and heterogeneous systems, and provide a more "customized" characterization of site conditions.

There is considerable variability in the scope, complexity, and degree of validation of available analytical and numerical models.

The majority of commercially available models address the leaching of contaminants from soil and/or movement of aqueous-phase contaminants in the unsaturated (vadose) or saturated (groundwater) zone. Newer models have also been developed to simulate multiphase transport, including vapor-phase transport in the unsaturated zone. Most models are deterministic; some are probabilistic.

### 6.3.1.2 Selection of Models

The key steps in the consideration, selection, and application of Predictive Models are summarized in Figure 6.1.

All models are premised on certain assumptions and conditions, and all are subject to certain limitations. At the present time, there are no universally accepted or even universally recommended models for all applications.

In evaluating and selecting a Predictive Model, the following factors should be considered:

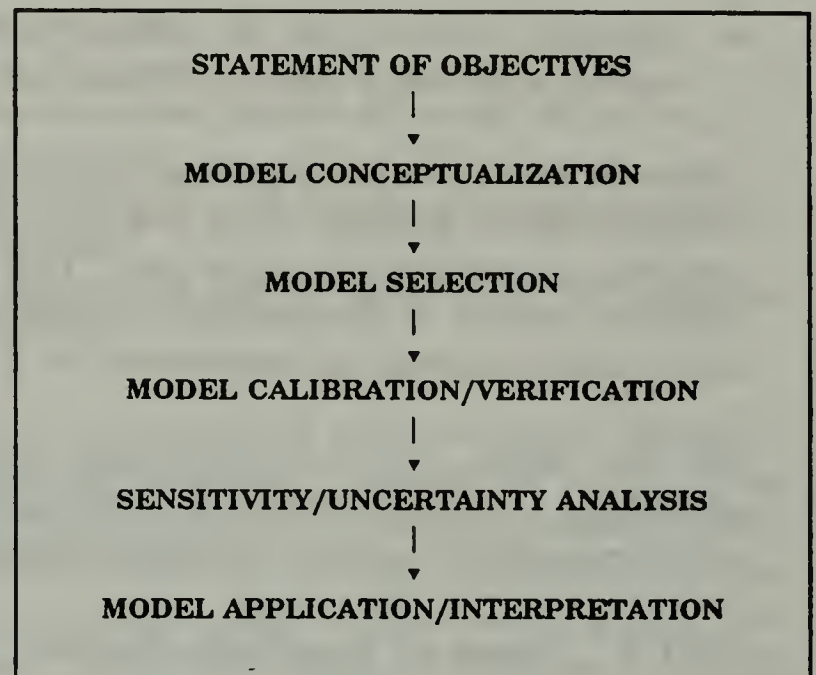


Figure 6.1

- (1) **Characterization and modeling objectives.** Study objective should be clearly defined early in the site evaluation process. Of prime consideration is whether a "screening" or a "detailed" evaluation is required, as this decision will affect not only the selection of a model, but also the nature, extent, and costs of necessary site investigation/data gathering activities. In many cases, a "screening" evaluation may be the most appropriate option, given study objectives, site conditions, and/or modeling and characterization uncertainties.
- (2) **Model Conceptualization/Selection.** It is important to ensure that selected models address those transport processes and domains that are of interest or importance at the site under evaluation. For example, some groundwater transport models can address multi-phase transport, which may be desirable at sites with Non Aqueous Phase Liquids and/or Volatile Organic Compounds. Similarly, some models incorporate a biological degradation component; this may be important when evaluating readily degradable contaminants like petroleum, but not important or necessary for sites with heavy metal contamination.
- (3) **Extent and quality of site/input data.** A detailed site evaluation using a numerical model generally requires a significant amount of site-specific data, for calibration/ validation purposes, and/or to otherwise yield meaningful modeling results. In the absence of such data, a "screening" analysis by an analytical model may be more appropriate.
- (4) **Model accuracy, validation, and verification.** These terms are used and defined differently by different parties, but concern the same central issue: the degree of certainty and documentation that exists or that needs to be obtained to demonstrate that a given model will accurately predict and characterize conditions *at the site under evaluation*.

Some models, particularly complex numerical models, will need to undergo a series of iterative calibration/validation processes. In other cases, a vendor or distributor may assert that a model has been "validated" or "verified"; such claims

should be closely scrutinized to ensure that sufficient documentation exists to support such an assertion, and that all model validation assumptions, conditions, and limitations are applicable *at the site under evaluation*, consistent with defined characterization and modeling objectives.

- (5) **Budget and resource availability.** The costs to obtain and use a Predictive Model, including ancillary costs associated with obtaining site assessment data needed for model calibration, validation, and/or model input, can be considerable, especially for detailed studies using numerical models. Moreover, it is very important that persons using a model be experienced and proficient in its use and interpretation; for complex numerical models, proficiency and experience is essential.

Ideally, the designation of study objectives, identification of risk characterization needs, and selection of a Predictive Model should be accomplished prior to the initiation or completion of comprehensive site assessment activities, in order to ensure/optimize data collection for modeling/risk characterization purposes.

### **6.3.1.3 Use, Application, and Interpretation of Predictive Models**

The selection of an appropriate model is only the first step in obtaining meaningful results: the second, and perhaps more important step, relates to the use and application of the selected model.

In many cases, a number of models will exist that will satisfy study objectives. Assuming that all models are sufficiently accurate, the input of identical data sets should yield similar results. In practice, however, significant differences in computed results arise, due to differences in how a modeler interprets and extrapolates available "raw data", and conceptualizes the modeled system.

In this regard, the following recommendations and considerations are offered:

- Given the uncertainties that exist using any model, conservative input values should be used wherever appropriate and reasonable. In some cases, it may be prudent or even cost-effective to use "worst case" values during a screening analysis, to rule out a pathway or exposures believed to be insignificant.
- A sensitivity or uncertainty analysis should be considered in cases where a "worst case" analysis is not performed. In such an analysis, input parameters are varied in order to determine variations in the predicted results. This information can then be used to determine which input parameters require accurate determination and which input parameters may be approximated with little loss in model accuracy. In situations where an accurate determination of sensitive input parameters cannot be obtained, such an analysis can be used to define the range of possible modeled outputs.
- A conceptualization of the modeled system and understanding of the transport processes being simulated is necessary to avoid making mistakes related to the "blind faith" acceptance of predicted results. Although it is difficult in some cases to relate abstract mathematical

relationships and solutions to real-world situations, predicted results that are inconsistent with technical insight or intuition should be a cause for concern and re-evaluation.

#### **6.3.1.4 Performance Standards for Predictive Modeling**

The use of Predictive Models in characterizing risk at disposal sites under the Massachusetts Contingency Plan are subject to the following standards and practices:

- Selected models must be scientifically valid and sufficiently documented.
- Predictive Models shall be selected, used, and applied in a manner that leads to a reasonably conservative and protective estimate of Exposure Point Concentrations.
- Data that is input to Predictive Models shall be of sufficient extent and quality to allow for the meaningful use, interpretation, and/or confirmation of modeling outputs, considering the sensitivity and uncertainty of modeling parameters, and the intended application of model outputs.
- All modeling and site-specific assumptions and conditions must be clearly articulated.
- All results must be clearly documented.

#### **6.3.1.5 Predictive Modeling & the MCP Method 1 Standards**

The Method 1 Standards were developed by DEP using certain predictive models and a number of conditions and assumptions. Parties contemplating the use of Predictive Models to modify these standards using a Method 2 analysis, or to develop alternative standards using a Method 3 analysis, may wish to review the specifics of this development process. Key Method 1 predictive modeling procedures and assumptions are summarized in Table 6.1. Complete details are provided in Background Documentation for the Development of the MCP Numerical Standards (April 1994).

Risk assessors are not limited to using the models employed by MADEP in setting the Method 1 standards, as long as the chosen model meets the performance criteria discussed above.

**Table 6.1**  
**Development of MCP Method 1 Standards**

**Leaching of Contaminants from Soil**

**MODEL(S):** SESOIL coupled with AT123D, as available through the USEPA Graphical Exposure Modeling System (GEMS) package, suitable for use on IBM-compatible personal computers (PCGEMS).

**APPROACH:** SESOIL was used to estimate seasonal leaching of contaminants from the vadose zone. This value was then input to AT123D to model flow through the saturated zone to a designated "point of compliance". Dilution and Attenuation Factors (DAF) were developed in this manner for 8 indicator chemicals, which were then used to develop a multiple linear regression model to relate the DAFs with partition coefficients ( $K_{oc}$ ) and Henry's Law Constants (H). This relationship was then used to estimate DAFs for other chemicals.

**KEY ASSUMPTIONS:**

- Contamination in vadose zone is 10 meters X 10 meters, 1 meter in depth (i.e. 100 m<sup>3</sup>), and is located 1 meter below the ground surface and 1 meter above the ground-water table.
- Groundwater "Point of Compliance" was surface of water table located 10 meters downgradient of contaminated soil.
- Sandy, pervious soils
- Moderate biodegradation rate for benzene; zero degradation rate for all other contaminants.

**Volatilization/Infiltration of Contaminants into Buildings**

**MODEL(S):** Based upon Heuristic Model developed by Johnson and Ettinger (1991)

**APPROACH:** Assumed partitioning at groundwater table = 10% of equilibrium condition predicted using Henry's Law. Assumed attenuation factor between inside and outside of building =  $5 \times 10^{-4}$  (Johnson and Ettinger).

**KEY ASSUMPTIONS:**

- Dissolved contaminants within 30 feet of building structure.
- Depth to groundwater 15 feet or less.
- Sandy, pervious soils.

**Discharge of Contaminated Groundwater to Surface Waters**

**MODEL(S):** None

**APPROACH:** Simple 10 fold dilution factor.

The following references are provided for risk assessors desiring a more detailed discussion of modeling and the selection of appropriate fate and transport models.

Mass DEP *Standard References for Monitoring Wells*, DEP Publication #WSC-310-91, Section 7.0 Groundwater Modeling.

US EPA, 1991 *Ground-Water Issue, Characterizing Soils for Hazardous Waste Site Assessments*. EPA/504/4-91/003. U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response, Washington, D.C.

US EPA, 1992 *Ground-Water Issue, Fundamentals of Ground-Water Modeling*. EPA/540/S-92/005. U.S. Environmental Protection Agency. Office of Solid Waste and Emergency Response, Washington, D.C.

US EPA, 1989 *Predicting Subsurface Contaminant transport and Transformation: Consideration for Model Selection and Field Validation*. EPA/600/2-89/045. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, Oklahoma.

US EPA, 1992 *Quality Assurance and Quality Control in the Development and Application of Ground-Water Models*. EPA/600/R-93/011. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

US EPA, 1993 *Compilation of Ground-Water Models*. EPA/600/R-93/118. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

US EPA, 1994 *Identification and Compilation of Unsaturated/Vadose Zone Models*. EPA/600/R-94/028. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

US EPA, 1994 *Evaluation of Unsaturated/Vadose Zone Models for Superfund Sites*. EPA/600/R-3/184. U.S. Environmental Protection Agency. Robert S. Kerr Environmental Research Laboratory, Ada, OK.

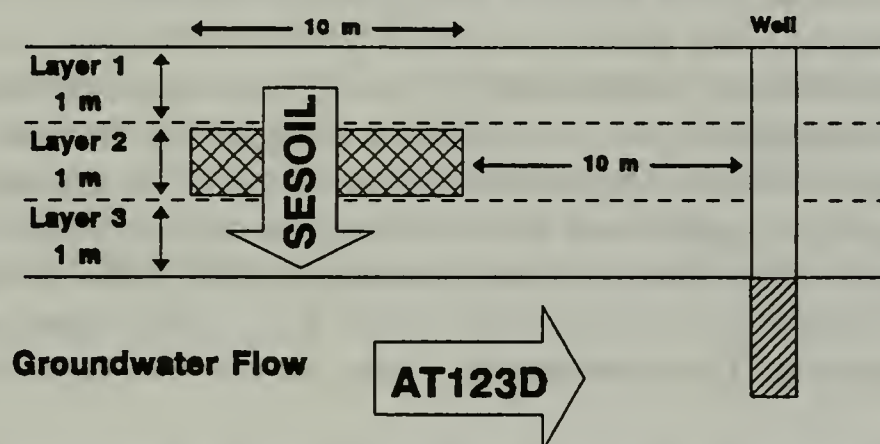
### 6.3.2 Leaching of Contaminants from Soil

The Method 1 Soil Standards (Tables 2, 3 and 4 of the MCP) consider the potential for contamination in soil leaching into the groundwater and resulting in adverse impacts on the aquifer. Remember that the underlying aquifer could be category GW-1, GW-2 and/or GW-3, so the soil standards are specific to the *combination* of soil and groundwater categories under consideration (e.g., S-1/GW-3, S-3/GW-1).

In setting these leaching- and health-based standards, the Department made certain assumptions about the characteristics of the soil and the properties of the aquifer. Two models were then used to develop the Method 1 Standards. The SESOIL (Seasonal Soil Compartment) Model was used to estimate seasonal leaching of site contaminants from the vadose zone. The value calculated from the SESOIL model was then input to the groundwater transport model (AT123D), to estimate the flow through the saturated zone and the contaminant concentration at a specified point of compliance ten meters downgradient from the site (Figure 6.2).

The parameters selected for input into the models were based upon assumptions about a "typical disposal site". (A brief summary of these parameters is given in Table 6.1 and a detailed description is given in *Background Documentation for the Development of the MCP Numerical Standards* (April 1994). This was done to make the approach as generalizable as possible to sites across the state. In so doing it was recognized that depending upon the individual characteristics of a particular site, the input parameters

## VERTICAL CROSS-SECTION



## HORIZONTAL CROSS-SECTION

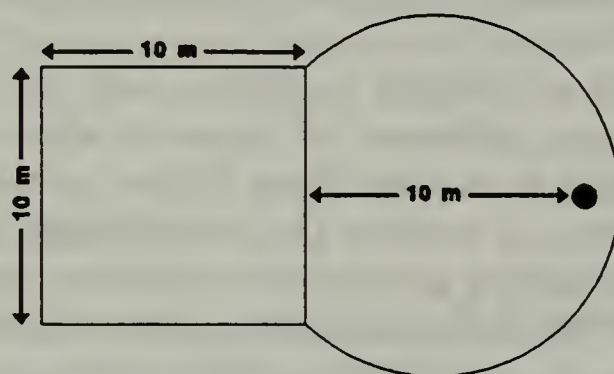


Figure 6.2

may be more or less applicable to any one location. In light of this, the following methods are identified in the MCP at 310 CMR 40.0985 (3) to demonstrate that the concentrations of oil and/or hazardous material in soil at the disposal site currently and in the foreseeable future will result in compliance with all MCP Method 1 or 2 Groundwater Standards:

- (a) fate and transport modeling that incorporates site-specific information on source mass and subsurface hydrogeological conditions; and/or
- (b) laboratory tests that demonstrate, under site conditions, the oil and/or hazardous material in the soil will not leach to groundwater at levels which exceed the applicable MCP Method 1 or 2 Groundwater Standards.

The result of a Method 2 modification of the Method 1 soil standards is one or more alternative soil standards which are both demonstrably protective of the site groundwater and equal to or less than the Direct Contact Exposure-Based Soil Concentrations listed in Table 5 of the MCP (310 CMR 40.0985(6)). If the calculated site-specific leaching-based concentration is greater than the Direct Contact Concentrations (or if the site-specific information indicates that material is not leaching to groundwater, and will not leach to groundwater, at significant levels), then the Direct Contact concentrations in Table 5 are adopted as the Method 2 soil standards (310 CMR 40.0982(2)).

### 6.3.3 Volatilization of Contaminants

The MCP Method 1 GW-2 Standards are based upon the potential for volatilization of contamination in groundwater into indoor air. As with the soil leaching modeling, certain assumptions were made to attempt to represent conditions at a "typical disposal site". The particular model utilized to develop the Method 1 Standards was the Heuristic Model developed by Johnson and Ettinger (1991). The development of GW-2 standards based upon this approach is described in Section 4.2 of the *Background Documentation for the Development of the MCP Numerical Standards* (April 1994).

Site-specific factors such as building conditions, soil type, depth to groundwater and depth to contamination may influence the degree to which vapors infiltrate a structure. The risk assessor may want to consider these factors, as well as any soil gas or indoor air measurements in determining whether the groundwater contamination is affecting the indoor air and when establishing groundwater concentrations of a chemical which would represent a condition of No Significant Risk for this exposure pathway.

The result of a Method 2 modification of the Method 1 GW-2 standards is one or more alternative groundwater standards which are both demonstrably protective of potential indoor air exposures and equal to or less than the groundwater Upper Concentration Limits listed in Table 6 of the MCP (310 CMR 40.0996(5)). If the calculated site-specific volatilization-based concentration is greater than the groundwater Upper Concentration Limit (or if the site-specific information indicates that material is not volatilizing, and will not volatilize, to indoor air at significant levels), then the Upper Concentration Limits in Table 6 are adopted as the Method 2 GW-2 standards (310 CMR 40.0982(4)).

### 6.3.4 Discharge to Surface Water

The MCP GW-3 standards consider potential impacts from the discharge of contaminated groundwater into a surface water body. The standards incorporate a simple dilution factor of ten (10) based upon the experience of MADEP Division of Water Pollution Control in writing groundwater and surface water discharge permits. The development of GW-3 standards based upon this approach is described in Section 4.3 of the

*Background Documentation for the Development of the MCP Numerical Standards (April 1994).*

Site-specific factors, such as the soil type, volume of contaminated groundwater and distance to the point of discharge to surface water may influence the concentration of oil or hazardous material in the groundwater at the point of discharge. The risk assessor may want to consider these factors in determining whether the groundwater concentration at the site will significantly affect surface water and when establishing a groundwater concentration (i.e., a Method 2 standard) that would represent a condition of No Significant Risk for this pathway.

The result of a Method 2 modification of the Method 1 GW-3 standards is one or more alternative groundwater standards which are both demonstrably protective of receiving surface water bodies and equal to or less than the groundwater Upper Concentration Limits listed in Table 6 of the MCP (310 CMR 40.0996(5)). If the calculated site-specific surface water risk-based concentration is greater than the groundwater Upper Concentration Limit (or if the site-specific information indicates that material is (and will) not discharge to a surface water body at significant levels), then the Upper Concentration Limits in Table 6 are adopted as the Method 2 GW-3 standards (310 CMR 40.0982(4)).

#### 6.4 RISK CHARACTERIZATION

The process for a Method 2 Risk Characterization will follow the same methodology as a Method 1 Risk Characterization (310 CMR 40.0988(1)), with the exception that at least some of the applicable standards will have been developed or modified using Method 2 procedures. Thus the documentation for a Method 2 risk characterization must:

- ▶ Identify the Human Receptors (310 CMR 40.0921)
- ▶ Identify the Environmental Receptors (310 CMR 40.0922)
- ▶ Identify the Site Activities and Uses (310 CMR 40.0923)
- ▶ Identify Exposure Points (310 CMR 40.0924 and 40.0973)
- ▶ Identify Exposure Pathways (310 CMR 40.0925)
- ▶ Identify Exposure Point Concentrations (310 CMR 40.0926 and 40.0973)
- ▶ Identify Site Groundwater and Soil Categories (310 CMR 40.0930)

- ▶ Identify Applicable Groundwater and Soil Standards (310 CMR 40.0973)
- ▶ Compare the Exposure Point Concentrations to Applicable Method 1 and Method 2 Standards (310 CMR 40.0988)
- ▶ Clearly State Conclusions of the Risk Characterization (40.0988).

These risk characterization steps are discussed in detail for Method 1 in Section 5.0 of this document, and the reader is referred there for specific requirements.

## REFERENCES FOR CHAPTER 6

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Calabrese, E.J., Kostecki, P.T. 1992. Risk Assessment and Environmental Fate Methodologies. Lewis Publishers.

Johnson, P.C., Ettinger, R.A. 1991. Heuristic Model for Predicting the Intrusion Rate of Contaminated Vapors into Buildings. Environmental Science and Technology 25:8-1445.

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Mercer, J.W., Faust, C.R. 1986. Ground-Water Modeling: An Overview. Ground-Water Modeling. National Water Works Association.

United States Environmental Protection Agency (USEPA) 1988. Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-Water Models. Office of Health and Environmental Assessment, Washington, D.C. EPA/600/8-88/075.



## 7.0 METHOD 3 - HUMAN HEALTH

This section provides guidance on conducting a Method 3 Human Health Risk Characterization. The human health evaluation is just one of four distinct assessments which comprise a complete Method 3 Risk Characterization: the risk to safety, public welfare and the environment must also be addressed. The most site-specific of the three risk characterization options available under the MCP, a Method 3 assessment is an option at all c.21E sites.

The specific regulations concerning the Method 3 risk characterization process begin at 310 CMR 40.0990 of the Massachusetts Contingency Plan. Readers are reminded that general requirements applicable or potentially applicable to all risk characterizations are found in 310 CMR 40.0900 through 40.0960, and are described in Section 1.0 through 4.0 of this guidance document.

The Method 3 human health risk characterization approach involves five steps: hazard identification, dose-response assessment, exposure assessment, risk characterization and uncertainty analysis.

**Hazard Identification** determines whether a substance causes adverse effects and identifies those effects. This step describes why the substance is of regulatory concern.

**The Dose-Response Assessment** describes the relationship between the level of exposure and the likelihood and/or severity of an adverse effect. Simply speaking, the dose-response information describes the toxicity of the substance.

**The Exposure Assessment** involves identifying potential routes of exposure; characterizing the populations exposed; and determining the frequency, duration and extent of exposure.

### *A Method 3 Risk Characterization Is Complete If...*

- Risk to Safety  
(Section 4.0)
- Risk to Human Health  
(Section 7.0)
- Risk to Public Welfare  
(Section 8.0)
- Risk to the Environment  
(Section 9.0)

### *...Are Evaluated*

The scope and level of effort needed to complete each component of a Method 3 Risk Characterization will vary depending upon site conditions.

The **Risk Characterization** combines information from the previous three steps to describe the type (e.g., carcinogenic or non-carcinogenic) and magnitude of risks to exposed populations. The resulting risks are then compared to the risk management criteria promulgated in the regulations.

The **Uncertainty Analysis** identifies the nature and, when possible, the magnitude of the uncertainty and variability inherent in the characterization of risks. The results of any risk assessment reflect scientific uncertainty resulting from limitations in available data and assumptions that are made in the absence of such data, and the variability in exposure and toxicological response expected given the diversity within the human population. The assumptions and limitations which are a part of all risk characterizations should be explicitly discussed.

Each of these risk assessment steps is described in detail in the following sections of this document.

It is important to remember that risk estimates generated in the risk assessment are not measures of actual or absolute risks. Rather, risk assessments are a tool - a method of providing valuable information regarding potential risks to public health and the environment. Risk assessment is used throughout the regulatory process to provide such information, whether it is to determine "How clean is clean enough?" at a disposal site, to develop drinking water standards for public water supplies, or to evaluate a proposed facility seeking a source permit.

The MCP is explicit in its interpretation of the significance of the risk estimates. The risk management philosophy inherent in the establishment of the risk limits is to ensure that no potential receptor groups would experience an excess lifetime cancer risk greater than the risk limit, regardless of the number of chemicals or exposure routes that exist at a site. The noncancer risk limit reflects a risk management decision that multiple-chemical, multiple-route exposures related to a disposal site will not exceed an estimated "allowable" dose - a dose which would not result in adverse health effects.

Under Method 3, remediation of the disposal site is required if: (1) Exposure Point Concentrations exceed any applicable or suitably analogous public health standards, *or* (2) the estimated cancer or non-cancer risks associated with exposure to oil or hazardous material exceed the Cumulative Receptor Risk Limits (310 CMR 40.0993(6)). Remedial alternatives must be evaluated to determine if they eliminate "Significant Risk" as defined in the MCP.

## 7.1 HAZARD IDENTIFICATION

The Hazard Identification portion of an MCP Method 3 risk characterization describes the hazards associated with each OHM which has been selected as a Contaminant of Concern. More specifically, the Hazard Identification discusses whether exposure to a particular contaminant can cause an increase of a particular adverse health effect and whether the adverse health effect is likely to occur in humans.

The Hazard Identification section of the Risk Assessment should contain: an identification of the OHMs which have been selected as Contaminants of Concern, a summary of the analytical data which have been collected for these OHMs presented by specific environmental medium, and a description of the potential health effects which may be associated with exposure to each OHM.

The description of the potential health effects associated with each contaminant is provided in a *Toxicity Profile*. A Toxicity Profile should be prepared for each Contaminant of Concern and presented in the documentation of the Risk Characterization.

Toxicity Profiles serve several purposes. They provide a summary of the potential adverse human health effects which may be associated with exposure to a particular contaminant and contain references for the dose-response assessment. Toxicity Profiles also serve as reference material for non-toxicologists who are involved with or interested in activities at the site and who want to understand the potential health impacts associated with contaminants at the site.

The information in Toxicity Profiles may also be used to group chemicals by health endpoint and mechanism of toxicity in order to estimate more detailed Hazard Indices. The reader should refer to Section 7.4.1 for more information on calculating endpoint-specific Hazard Indices.

In general, a Toxicity Profile is a comprehensive, in-depth profile of the toxicokinetics, human and animal mechanisms of toxicity, genotoxicity, carcinogenicity, and developmental/reproductive toxicity for the chemical of interest. A Toxicity Profile should also address Structure Activity relationships and interaction with other chemicals, as appropriate. In preparing the Toxicity Profile, the risk assessor should rely on credible, peer-reviewed sources of information such as controlled, epidemiologic investigations, clinical trials, experimental animal studies, metabolic and pharmacokinetic experiments, *in vitro* studies and structure-activity studies. All references should be provided to document the sources of information used to prepare the Toxicity Profile.

The scope and level of detail of a Toxicity Profile will vary depending upon the nature and quantity of information available for a particular chemical. For many substances (e.g.,

chemicals for which Method 1 standards have been developed) toxicological information is readily available from many sources, and repetition of that information in great detail in the Toxicity Profile is not necessary. For such cases a short descriptive summary of the known health effects associated with the chemical of interest and the basis for any existing standards or guidelines would be sufficient. The primary purpose of such a descriptive summary is to provide information to the public in a readily available form.

## 7.2 DOSE RESPONSE ASSESSMENT

The dose-response assessment describes the observed effects in humans and/or laboratory animals associated with particular exposures (or doses) of the chemical of concern. This information is obtained from published literature describing epidemiologic or toxicologic studies involving the particular chemical. For most chemicals reported at c.21E disposal sites, the dose-response information needed to conduct a risk assessment may be found in secondary sources published by the USEPA or other government agencies, as described below.

The dose-response relationship(s) for each OHM which has been selected as a Chemical of Concern must be identified in the risk assessment report. This information is later coupled with knowledge of the nature and magnitude of potential exposures to characterize risk.

The dose-response information may be divided into three major categories:

- Toxicity information associated with threshold (non-carcinogenic) health effects.
- Toxicity information concerning carcinogenicity, either from human epidemiologic data or from laboratory studies.
- The Relative Absorption Factors (RAFs) used to relate the toxicity information identified from the literature to the exposure pathways of concern at the disposal site under investigation

All the chemicals selected as Contaminants Of Concern should be evaluated for potential *non-carcinogenic* health effects. In addition, any substance considered to be a *known, probable, or possible* human carcinogen (as designated by EPA) should also be evaluated for its potential carcinogenic effect. The classification of a chemical as a carcinogen does not preclude an evaluation of that same chemical for potential non-carcinogenic health risks.

### 7.2.1 Threshold Effects

For non-carcinogenic health effects, it is believed that a dose (or exposure) level exists at and below which no adverse health effects would be expected. Such a level is referred to as a *threshold dose*. In theory, the threshold dose would be safe for all receptors who might be exposed at that level.

The goal of the dose response assessment is to identify the threshold dose, or a close approximation, given the toxicological information currently available. It may be impossible, however, to specify this theoretical threshold dose for a given chemical due to the inadequacy of the scientific data. Ideally, the threshold dose would be identified from large and well-run human epidemiological and toxicological studies. Unfortunately, such studies are uncommon as they are difficult to conduct, expensive, time-consuming, and often pose ethical concerns. It is possible to approximate this threshold dose in a health-protective manner that accounts for the data limitations by identifying a *sub-threshold* dose: such a value is typically derived from the *No Observable Adverse Effects Level* (NOAEL) of an animal study by application of uncertainty factors (UF) and a modifying factor (MF) (Farland and Dourson, 1992). Uncertainty Factors are applied to account for interspecies variation, exposure duration and protection of sensitive populations. Additional Uncertainty Factors may be applied if the toxicological study identified a *Lowest Observable Adverse Effects Level*, or LOAEL, rather than a NOAEL. Each Uncertainty Factor is typically equal to a factor of ten, and the product of all the Uncertainty Factors may be as high as 10,000 ( $10 \times 10 \times 10 \times 10$ ). A Modifying Factor may be applied to reflect additional uncertainties in the critical study and the entire data base not addressed by the Uncertainty Factor. The value of the Modifying Factor is greater than zero and less than or equal to ten; the default value for the Modifying Factor is one. Important factors to consider when identifying and using such a sub-threshold dose include, at a minimum:

- the route of administration from the study (inhalation, oral, dermal contact, etc...);
- the duration of exposure to that dose (lifetime, chronic, subchronic, or acute exposure);
- the absorption efficiency (if any) used to calculate that dose; and
- the age of the person receiving the dose.

The subthreshold dose in units of mg/kg/day (with uncertainty spanning perhaps an order of magnitude or greater) to which daily exposure of a human population, including sensitive subgroups, is likely to be free of appreciable risk of deleterious effects during a lifetime is termed a *Reference Dose* (RfD) (Barnes and Dourson, 1988). The RfD is derived using the following equation:

$$RfD_{(mg/kg/day)} = \frac{NOAEL \text{ or } LOAEL}{U.F. \text{ and/or } MF} \quad (7-1)$$

USEPA (1991) has also proposed a **Reference Dose for developmental toxicity** ( $RfD_{DT}$ ). The  $RfD_{DT}$  is based on a NOAEL derived from short-duration exposures typically used in developmental studies. Uncertainty factors for developmental toxicity generally include a tenfold factor for interspecies variation and a tenfold factor for intraspecies variation; in general an uncertainty factor is not applied to account for duration of exposure. Additional uncertainty factors may be applied due to a variety of uncertainties in the data base (Farland and Dourson, 1992).

A **Reference Concentration** ( $RfC$ , in units of  $mg/m^3$ ) is the inhalation exposure concentration (with uncertainty spanning perhaps an order of magnitude or greater) to which daily exposure of a human population, including sensitive populations, is likely to be free of appreciable effects. Interim methods for development of inhalation reference concentrations (USEPA, 1990) describe the conversion of the experimental exposure NOAEL to human equivalent concentrations ( $NOAEL_{HEC}$ ). The conversion is specific both to the type of inhaled agent (particle or gas) and to the observed effect (respiratory or systemic) and adjusts for dosimetric differences between various experimental species and humans. Once the  $NOAEL_{HEC}$  is identified, the same equation used to estimate the  $RfD$  is used to calculate the inhalation  $RfC$  with the application of similar, although not identical, uncertainty factors (Farland and Dourson, 1992). Conversion of an  $RfC$  to an inhalation  $RfD$  (in units of  $mg/kg/day$ ) is not recommended.

There are a number of different sources of subthreshold toxicity values. When selecting toxicity information for use in quantitative risk assessment, the risk assessor should ensure that the information is appropriate for the assessment being conducted and that it is up-to-date. Note that sources differ in the frequency at which they are updated and the level of review they receive. The Massachusetts Contingency Plan requires that primary consideration be given to information developed by the U.S. Environmental Protection Agency (310 CMR 40.0993(5)(a)).

The following presents a list of sources of toxicity information in the order of preference:

- (1) **Integrated Risk Information System (IRIS)** - IRIS is an USEPA data base that contains only those  $RfDs/RfCs$  which represent a consensus judgement of USEPA  $RfD/RfC$  Workgroup which is composed of scientists from various EPA offices and the Office of Research and Development. It is the preferred source of toxicity information. The IRIS database is updated monthly and is available on-line. For information on how to access IRIS, call IRIS user support at (513) 569-7254.

- (2) **Health Effects Assessment Summary Tables (HEAST)** - HEAST is prepared by USEPA's Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH. HEAST contains almost entirely *provisional* toxicity values. These values have undergone review by individual USEPA program offices, but are not recognized as agency-wide consensus values. HEAST is scheduled to be updated quarterly and can be obtained by contacting the National Technical Information Services (NTIS) Subscriptions Department at (703) 487-4630.
- (3) **Other sources.** When information is not available in IRIS or HEAST, the following sources may be reviewed to determine whether comparable values exist and whether those values are appropriate for quantitative risk assessment.

**Toxicity Values Developed by MADEP, ORS** - The Office of Research and Standards develops chronic and subchronic RfDs and RfCs for some OHMs for which no values are available in IRIS or HEAST. These values are based on available toxicological data and standard USEPA approaches for developing reference doses for threshold effects. The list of chemicals includes a number of carcinogens for which USEPA has not derived non-cancer toxicity values. These values can be accessed through the MA DEP Bulletin Board.

**Agency for Toxic Substances Disease Registry (ATSDR)** - ATSDR produces Toxicological Profiles for 275 hazardous substances found at NPL sites. The priority list of hazardous substances is published in the Federal Register. An announcement of the release of draft Toxicological Profile documents appears in the Federal Register and the documents are available from ATSDR. Final toxicological profiles which incorporate reviewers comments, are available from the National Technical Information Service (NTIS) at (800) 553-6847 or (703) 487-4650.

In the toxicological profiles, ATSDR develops *Minimal Risk Levels* (MRLs) for threshold effects of some chemicals. These values are updated when the profiles are revised, if appropriate. An MRL is defined as an estimate of the daily human exposure to a substance that is likely to be free of appreciable risk of adverse noncancerous effects over a specified duration of exposure. MRLs are derived using the modified risk assessment methodology the U.S. EPA uses to derive reference doses and reference concentrations for lifetime exposure.

**Allowable Threshold Concentration (ATC)** - The "*Allowable Threshold Concentrations*" are values roughly equivalent to the reference concentration, but they are derived from the Threshold Effects Exposure Limit (TEL) described in CHEM (MA DEP, 1990). (The TEL value represents 20% of an allowable concentration, or ATC. Thus the ATC is equal to five times the TEL. The TEL was derived in a manner considering children to be the most sensitive potential receptors.) The ATC is a concentration of the chemical in air which would not be expected to result in adverse non-carcinogenic health effects. The ATC is derived considering acute and chronic threshold health endpoints, including reproductive effects. These values can be accessed through the MA DEP Bulletin Board.

### **Allowable Doses Back-Calculated From Drinking Water Standards and Guidelines**

Drinking water standards and guidelines, which give the allowable concentration of a contaminant in drinking water supplies include: the Maximum Contaminant Level Goal (MCLG), the Maximum Contaminant Level (MCL), and Health Advisories (HAs). An allowable daily intake (ADI) comparable to an RfD may be obtained by back-calculation, using the same exposure assumptions used to develop the standard or guideline. It

is imperative that the assumptions used to develop the standard or guideline be known before an RfD is calculated.

### **Back-calculating From Standards**

When back-calculating from a concentration to a dose, the risk assessor must always use the exposure assumptions on which the concentration is based. For example, if a drinking water standard was derived using a body weight of 70 kg and a water intake rate of 2 liters/day, those factors must be used in back-calculating an allowable daily dose.

Site-specific exposure assumptions (such as a child's body weight and water intake rate) would then be considered in the risk assessment itself to evaluate the potential risk posed by the contamination.

A list of MCLs, MCLGs and HAs is available from USEPA by calling the Safe Drinking Water Hotline (1-800-426-4791). The list is updated twice per year. These values are also available in a chemical's IRIS file.

**MCLGs** - MCLGs are non-enforceable concentrations of a drinking water contaminant that are protective against adverse human health effects and allow an adequate margin of safety. MCLGs for substances considered to be carcinogenic are set at zero because USEPA assumes that any level of exposure is associated with some level of risk. MCLGs for substances not treated as known or probable human carcinogens are based upon chronic toxicity or other health data and applied uncertainty data. *Back calculation from the MCLG is only appropriate for use in the evaluation of compounds not considered Weight-of-Evidence Group A or B carcinogens.* Documentation for MCLGs is found in the preamble to the final rule for each OHM in the Federal Register.

**MCLs** - MCLs are the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. MCLs are enforceable standards that are set as close to MCLGs as feasible. MCLs consider factors which are not strictly health based, such as treatment technology and cost. Thus, the basis for an MCL must be carefully examined before an MCL is used to derive an RfD. Generally, an MCL is not used to derive an RfD.

**Health Advisories** - Health Advisories (HAs) describe concentrations of drinking water contaminants at which adverse non-carcinogenic health effects would not be expected to occur over specific exposure durations. HAs are developed for 1-day, 10-day, longer term (generally up to 2 years), and lifetime exposures based only on data describing non-carcinogenic endpoints of toxicity. For those substances which are known or probable human carcinogens, HAs for lifetime exposure are not derived. The documentation for

each HA should be consulted before proceeding with any calculations. Documentation for HAs is available through the Education Research Information Clearinghouse (ERIC), (614) 292-6717.

**Allowable Doses Back-Calculated From Ambient Water Quality Criteria** - Ambient Water Quality Criteria (AWQC) are developed by the USEPA Office of Water Regulations and Standards per Section 304(a)(1) of the Clean Water Act of 1977. The AWQC consider both toxicity to aquatic life and human health effects. The AWQC do not consider technical feasibility or cost and may be used to derive a chronic sub-threshold dose for use in a risk assessment. However, it must be noted that the AWQC incorporate factors which account for exposure via both drinking water ingestion and consumption of contaminated fish. The documentation for each AWQC should be consulted before proceeding with any calculations and are available through the National Technical Information Service (NTIS) at (800) 336-4700. Individual AWQC are listed in IRIS.

- (4) **Calculation of a dose-response value using toxicity information from the literature.** Dose-response values may be derived by a qualified risk assessor or toxicologist if none of the above sources provides a toxicity value, but adequate toxicity studies are available, or if more recent, credible and relevant data becomes available. USEPA approaches to development of RfDs are described in *Risk Assessment Guidance for Superfund* (USEPA, 1989) and in Appendix A to IRIS. Approaches to the development of RfCs are described in *Interim Methods for Development of Inhalation Reference Doses* (USEPA, 1991). The review and approval by the Department of such a proposed value would depend upon the justification and documentation provided to support it. The development of an alternative value when a USEPA or MA DEP derived reference dose or reference concentration is available is rarely justifiable and the risk assessor should contact the MA DEP Office of Research and Standards early on in the site assessment process for prior approval before proceeding.

## 7.2.2 Carcinogenic Effects

Unlike non-carcinogenic health effects, the dose-response assessment for carcinogens assumes that there is no threshold dose for carcinogenicity; that there is no dose of a carcinogenic substance (other than no exposure) which is associated with zero risk. USEPA evaluates available toxicity data and, based on this evaluation, the chemical is assigned to a weight-of-evidence class. The system for characterizing the overall weight of evidence for a chemical's carcinogenicity developed by USEPA is based on the availability of animal, human, and other supportive data (USEPA, 1986). The weight-of-evidence classification rates the likelihood that an agent is a human carcinogen, and it may qualitatively affect the interpretation of potential health risks. Three major factors are considered in characterizing the overall weight-of-evidence for carcinogenicity: (1) the quality of evidence from human studies, (2) the quality of evidence from animal studies, and (3) other supportive information, such as mutagenicity data and structure-activity data. The five categories of the USEPA's final classification scheme (adapted

from an approach taken by the International Agency for Research on Cancer) are described in Table 7.1.

Table 7.1

The ability of a chemical to increase the incidence of cancer in a target population is described by one of two measures: the cancer *slope factor* or the *unit risk*. Cancer Slope Factors or Unit Risks are typically calculated for chemicals in Groups A, B1 and B2. Slope factors for chemicals in Group C are calculated on a case-by-case basis.

The cancer Slope Factor (CSF) for a chemical is derived by the USEPA's Cancer Assessment Group (CAG). Using mathematical extrapolation models, commonly the linearized multistage model, the largest possible linear slope (within the 95% Confidence Limit)

consistent with the available data is estimated at low extrapolated doses. For some chemicals, human epidemiologic data are the basis of an estimate of the carcinogenic potency, although the most common basis of these values is an animal study. The CSF is expressed as the risk per unit dose, and is typically given in units of (mg/kg/day)<sup>-1</sup>. Use of the slope factor assumes that the calculated dose received is expressed as a lifetime average.

The Unit Risk (UR) is the upper 95% Confidence Limit of the mean incremental lifetime cancer risk estimated to result from lifetime exposure to an agent if it is in the air at a concentration of 1 µg/m<sup>3</sup> or in the drinking water at a concentration of 1 µg/L. These values are used in lieu of the chemical's slope factor when an estimate of a lifetime average concentration of the chemical is available.

There are a number of different sources of CSFs and URs. When selecting this information for use in quantitative risk assessment, the risk assessor should ensure that

### USEPA Weight of Evidence Classification

**Group A - Human Carcinogen:** This category indicates there is sufficient evidence from epidemiological studies to support a causal association between an agent and human cancer.

**Group B - Probable Human Carcinogen:** This category generally indicates there is at least limited evidence from epidemiologic studies of carcinogenicity to humans (Group B1) or that, in the absence of data on humans, there is sufficient evidence of carcinogenicity in animals (Group B2).

**Group C - Possible Human Carcinogen:** This category indicates that there is limited evidence of carcinogenicity in animals in the absence of data on humans.

**Group D - Not Classified:** This category indicates that the evidence for carcinogenicity in animals is inadequate, or no data are available.

**Group E - No Evidence of Carcinogenicity to Humans:** This category indicates that there is evidence of noncarcinogenicity in at least two adequate animal tests in different species or in both epidemiologic and animal studies.

the information is appropriate for the assessment being conducted and that it is up-to-date. Note that sources differ in the frequency at which they are updated and the level of review they receive. The Massachusetts Contingency Plan requires that primary consideration be given to information developed by the U.S. Environmental Protection Agency (310 CMR 40.0993(5)(a)).

Preferred sources for cancer slope factors or unit risk values are:

- (1) **Integrated Risk Information System (IRIS)** - The IRIS data base contains only those CSFs or URs which represent a consensus judgement of the USEPA Carcinogen Risk Assessment Verification Endeavor (CRAVE) which is composed of scientists from various EPA offices and the Office of Research and Development. It is the preferred source of toxicity information. The IRIS database is updated monthly and is available on-line. For information on how to access IRIS, call IRIS user support at (513) 569-7254.
- (2) **Health Effects Assessment Summary Tables (HEAST)** - HEAST contains values that have received some form of review by USEPA, but have not been verified and are considered provisional. HEAST is prepared by USEPA's Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH. HEAST is scheduled to be updated quarterly and can be obtained by contacting the National Technical Information Services (NTIS) Subscriptions Department at (703) 487-4630.
- (3) **Other Sources** - When information is not available in IRIS or HEAST, the following sources may be reviewed to determine whether comparable values exist and whether those values are appropriate for quantitative risk assessment.

**California Environmental Protection Agency (Cal/EPA)** - Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA), Department of Pesticide Regulation (DPR) and Department of Toxic Substances Control (DTSC) develop or approve cancer potency factors for use in risk assessments and as the basis for regulatory action. A list of available cancer potency factors is revised semiannually and can be obtained from OEHHA's Hazardous Waste Toxicology Section, at (916) 324-7572.

**Toxicity Values Developed by MA DEP/ORS** - The Office of Research and Standards may develop CSFs and URs for chemicals for which no values are available in IRIS or HEAST. When available, these values can be accessed through the MA DEP Bulletin Board.

- (4) **Calculation of a slope factor or unit risk value using toxicity information from the literature.** CSFs and URs may be derived by a qualified risk assessor or toxicologist if none of the above sources provides a toxicity value, but adequate toxicity studies are available, or if more recent, credible and relevant data becomes available. USEPA approaches to development of cancer slope factors are described in several documents (USEPA, 1989a; USEPA, 1986) and in Appendix B to IRIS. The review and approval by the Department of such a proposed value would depend upon the justification and documentation provided to support it. The development

of an alternative value when a USEPA derived CSF or UR is available in IRIS or HEAST is rarely justifiable and the risk assessor should contact the MA DEP Office of Research and Standards early on in the site assessment process for prior approval before proceeding.

### 7.2.3 Relative Absorption Factors (RAFs)

The Relative Absorption Factor (RAF) is used to account for differences in the absorption of a COC under assumed exposure conditions at the site (exposure route and matrix) relative to the absorption of the COC under the experimental conditions upon which the dose-response value is based. RAFs are used *in lieu of absorption efficiencies* to ensure that the exposures evaluated at the disposal site are comparable to the toxicity information identified in the literature.

The reference doses, reference concentrations, slope factors and unit risks used in quantitative risk assessment are typically based upon controlled laboratory experiments in which animal test species are exposed in some manner to the chemical under study. Many important features vary from study to study: the test animal may vary (e.g., mice, rats, rabbits or even humans may be used); the chemical may be administered orally, dermally, via inhalation or injected; and the material may be administered in different matrices (e.g., neat, dissolved in oil or mixed with food). At disposal sites, the exposures of concern also vary widely and rarely correspond to the exact conditions under which the toxicity information was derived. Typical site-related exposure pathways include the incidental ingestion of contaminated soil by young children and the dermal absorption of a substance from surface water.

The RAF is used to adjust the calculated exposure (e.g., the soil ingestion exposure of a child) in such a way that it is comparable to the toxicity information (e.g., derived from a study in which rats were administered by gavage a chemical dissolved in olive oil).

A unique RAF should be determined or estimated for a chemical for each combination of toxicity value and route of exposure. This means that multiple RAFs may be required in order to conduct the quantitative risk assessment. To estimate an RAF, two factors must be identified:

- the absorption efficiency for the chemical via the route and medium of exposure being evaluated for the disposal site, and
- the absorption efficiency for the route and medium of exposure in the experimental study which is the basis of the dose-response value for the chemical in question.

Thus, the RAF adjusts the dose (or exposure) estimates based on these *two* absorption efficiencies. The RAF is calculated as follows:

$$RAF = \frac{\text{Absorption Efficiency}_{\text{SITE route/medium of exposure}}}{\text{Absorption Efficiency}_{\text{STUDY route/medium of exposure}}} \quad (7-2)$$

It is *very* important to determine whether the toxicity value is based on a *absorbed* or *applied* dose. The above equation is for a dose response value based on an applied dose. If the dose response value has been derived from an absorbed dose, then the RAF is simply equal to the absorption efficiency via the route and medium under consideration.

An example of the calculation of an RAF for dermal exposure to benzo(a)pyrene (carcinogenic effects) in soil is presented in Example 7.1 (taken from MADEP, 1992b).

RAFTs developed by MADEP Office of Research and Standards staff are available through the MA DEP's Risk Assessment Bulletin Board. A number of DEP derived RAFTs are listed in the Toxicity Information section of the *Risk Assessment ShortForm - Residential Scenario* and accompanying documentation (MADEP, 1992b). USEPA's Risk Assessment Guidance for Superfund (1989a), Appendix A also provides guidance for the "Adjustments For Absorption Efficiency" - a process similar to the development of RAFTs.

The risk assessor is reminded that an absorption efficiency (or absorption factor) which does not consider derivation of the toxicity values (Reference Dose, Reference Concentration, Slope Factor or Unit Risk) is not an RAFT.

#### 7.2.4 Groups of Chemicals

The discussion in this section has focused on the toxicity information available for specific chemicals. There are several groups of closely related compounds for which alternative approaches to the identification of dose-response values have been proposed and specific guidance has been requested. These groups include:

- Chlorinated dioxins and furans
- Polycyclic Aromatic Hydrocarbons (PAHs)
- Polychlorinated Biphenyls (PCBs)
- Total Petroleum Hydrocarbons (TPH)

Approaches to evaluating the toxicity of each of these groups is described below.

## Example 7.1

### EXAMPLE DERIVATION: RAF for the Cancer Risk Evaluation of Site Soil Dermal Exposures

The oral slope factor for benzo(a)pyrene (B[a]P) is listed in IRIS as  $7.3 \text{ (mg/kg/day)}^{-1}$  and is based on a dietary study in mice. The oral absorption of  $^{14}\text{C}$ -labeled B[a]P, dissolved in peanut oil and administered by gavage, was studied in rats (Hecht et al., 1979). Absorption was determined by recovery of label in urine and feces. Unchanged B[a]P recovered in feces was estimated at 9% of the total dose, with all other fecal radioactivity (85% of applied dose) recovered as metabolites. This suggests an oral absorption efficiency of 91%.

The percutaneous absorption of  $^{14}\text{C}$ -B[a]P was studied in vivo in Swiss Webster mice (Sanders et al., 1986) and in Sprague-Dawley rats (Yang et al., 1986). Absorption was determined by analyzing radioactivity in urine, feces and tissues, and by analysis of residual label at the site of application. Dermal absorption efficiency was measured as 40% (in mice) and 6% (in rats) in 24 hrs. The higher value of 40% is selected as a protective estimate for human dermal exposure to pure compound. In vitro estimates are lower, ranging from 0.1%-15% in humans and animals (Kao et al., 1985; Kao et al., 1988) and are not considered applicable to human exposure. The in vivo percutaneous absorption of soil-adsorbed B[a]P was determined in rats by Yang et al. (1989). The range of absorbed doses was 1.3% - 9.2% depending on the amount of soil applied. More efficient absorption occurred at lower soil application rates. Wester et al. (1990) confirms a low absorption for soil-associated B[a]P in the rhesus monkey with a range of 9% - 18%. The upper limit of 18% is selected as a protective estimate for human exposure to B[a]P contaminated soil.

The dermal penetration of B[a]P, applied as a complex organic mixture, seems to be representative of the dermal penetration of other PAHs examined in this study (Dankovic et al., 1989) including pyrene, benzantracene, benzo(a)fluorene, methylchrysene, chrysene, benzo(a)fluoranthene and benzo(e)pyrene. The disappearance half-life of B[a]P was 6.7 hours with the other PAHs ranging from 5.0 - 8.8 hours. The disappearance half-life of B[a]P was decreased to 3 hours when pure B[a]P was applied to skin in acetone. These data suggest a 50% decrease in dermal absorption of B[a]P when applied as an environmental mixture (20%) rather than as neat compound (40%). This compares closely with the upper limit of 18% dermal absorption efficiency selected from the study of Wester et al. (1990) for soil-associated B[a]P.

The RAF specific to the cancer risk evaluation of for soil dermal contact exposures would be the ratio:

$$\text{Absorption Efficiency}_{\text{B[a]P from soil via dermal contact}} \div \text{Absorption Efficiency}_{\text{B[a]P via oral exposure}}$$
$$\text{RAF} = 0.18 \div 0.91 = 0.2$$

#### 7.2.4.1 Chlorinated Dioxins and Furans

Polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) comprise a family of chemicals containing 210 specific monochlorinated and polychlorinated congeners. In 1987, USEPA formally adopted an interim procedure for estimating risks associated with complex environmental mixtures containing PCDDs and PCDFs (Bellin and Barnes, 1987). The procedure used a set of toxicity equivalency factors (TEFs) to convert the concentration of congeners into an equivalent concentration of 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD), the most toxic of the 210 congeners. The TEFs have been reviewed and updated periodically, the most recent update being USEPA (1989b) and MADEP (Silverman and Hutcheson, 1991).

A list of current TEFs is presented in Table 7.2. Documentation of the derivation of these toxicity equivalency factors is available from the MADEP Office of Research and Standards and may be accessed through the MA DEP Bulletin Board.

Table 7.2

MADEP Derived Toxicity Equivalency Factors (TEFs) for Polychlorinated Dioxins and Dibenzofurans	
Compound	TEF
<b>DIOXINS:</b>	
Mono-, Di- and Trichlorinated dibenzo-p-dioxins . . . . .	0.001
2,3,7,8-Tetrachlorinated dibenzo-p-dioxin .	1
Other tetrachlorinated dibenzo-p-dioxins .	0.01
2,3,7,8-Pentachlorinated dibenzo-p-dioxins	0.5
Other Pentachlorinated dibenzo-p-dioxins .	0.05
2,3,7,8-Hexachlorinated dibenzo-p-dioxins	0.1
Other Hexachlorinated dibenzo-p-dioxins .	0.01
2,3,7,8-Heptachlorinated dibenzo-p-dioxins	0.1
Other Heptachlorinated dibenzo-p-dioxins	0.01
Octochlorinated dibenzo-p-dioxin . . . . .	0.001
<b>FURANS:</b>	
Mono-, Di- and Trichlorinated dibenzofurans . . . . .	0.001
2,3,7,8-Tetrachlorinated dibenzofuran . . .	0.1
Other Tetrachlorinated dibenzofurans . . .	0.01
2,3,7,8-Pentachlorinated dibenzofurans . .	0.5
Other Pentachlorinated dibenzofurans . . .	0.05
2,3,7,8-Hexachlorinated dibenzofurans . . .	0.1
Other Hexachlorinated dibenzofurans . . .	0.01
2,3,7,8-Heptachlorinated dibenzofurans . .	0.1
Other Heptachlorinated dibenzofurans . . .	0.01
Octochlorinated dibenzofurans . . . . .	0.001
<i>from MADEP (Silverman and Hutcheson, 1991)</i>	

#### 7.2.4.2 Polycyclic Aromatic Hydrocarbons (PAHs)

Polycyclic aromatic hydrocarbons are a class of structurally similar chemical compounds characterized by the presence of fused aromatic rings. PAHs are typically formed during the incomplete burning of organic material including coal, oil, gasoline and garbage. PAHs are also found in crude oil, coal tar, creosote and asphalt. PAHs are associated

Table 7.3

with human activities (the combustion of fossil fuels) and natural occurrences (such as forest fires), and they are considered to be ubiquitous in the environment at some level.

PAHs are often discussed as a group because they are commonly found as mixtures of two or more compounds in the environment. In addition, they are often treated similarly in risk assessments due to their similar structures and toxicities. It should be noted that, while PAHs are often discussed as a group, the individual chemicals are evaluated as separate chemicals in the risk characterization. There are over 100 chemicals in this family of compounds, although a smaller number are routinely reported at disposal sites (Table 7.3). *The PAH's which are often present at sites but are unreported may result in the underestimation of potential risks.*

Among the polycyclic aromatic hydrocarbons, the USEPA (IRIS, 1993) has classified seven chemicals as *probable human carcinogens* (identified in Table 7.3 as USEPA Class B2). The classification of PAHs by the International Agency for Research on Cancer (IARC) is fairly consistent with that of the EPA. PAH's which are considered unclassified (either N/A, D or 3 in Table 7.3) may also contribute to carcinogenic risk (Nisbet and LaGoy, 1992) and should not necessarily be assumed to be "*noncarcinogens*" which would be USEPA Class E.

All PAHs identified as contaminants of concern should be evaluated in terms of potential noncancer risk. *Remember that the carcinogenic PAHs may also be associated with noncancer health effects and must be included in this evaluation.*

**PAH's Commonly Reported at c.21E  
Disposal Sites and Carcinogenicity  
Weight-of-Evidence Classifications**

	USEPA <sup>1</sup>	IARC <sup>2</sup>
Acenaphthene . . . . .	N/A . . . . .	N/A
Acenaphthylene . . . . .	D . . . . .	N/A
Anthracene . . . . .	D . . . . .	3
Benz(a)anthracene . . . . .	B2 . . . . .	2A
Benz(a)pyrene . . . . .	B2 . . . . .	2A
Benzo(e)pyrene . . . . .	N/A . . . . .	3
Benzo(b)fluoranthene . . . . .	B2 . . . . .	2B
Benzo(g,h,i)perylene . . . . .	N/A . . . . .	3
Benzo(j)fluoranthene . . . . .	N/A . . . . .	2B
Benzo(k)fluoranthene . . . . .	B2 . . . . .	2B
Chrysene . . . . .	B2 . . . . .	3
Dibenz(a,h,)anthracene . . . . .	B2 . . . . .	N/A
Fluoranthene . . . . .	D . . . . .	3
Fluorene . . . . .	N/A . . . . .	3
Indeno(1,2,3-cd)pyrene . . . . .	B2 . . . . .	2B
2-Methylnaphthalene . . . . .	N/A . . . . .	N/A
Naphthalene . . . . .	D . . . . .	3
Phenanthrene . . . . .	D . . . . .	3
Pyrene . . . . .	D . . . . .	3

- 1 - U.S. Environmental Protection Agency. B2: Probable Human Carcinogen; D: Not Classifiable  
 2 - International Agency for Research on Cancer. 2A: Probable Human Carcinogen; 2B: Possible Human Carcinogen; 3: Not Classifiable  
 N/A - Not Available

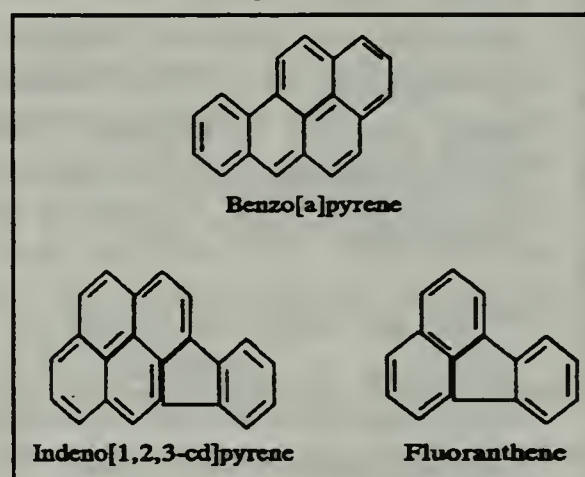
Historically, risk assessments involving PAHs become problematic due to the general lack of toxicity information available for many of the compounds reported at disposal sites. The following paragraphs discuss the MA DEP recommended approaches for the evaluation of cancer and noncancer risk of harm posed by exposure to polycyclic aromatic hydrocarbons.

### PAH Cancer Risk:

Until recently the only cancer slope factor the USEPA published for PAH's was for the chemical benzo[a]pyrene (B[a]P). In the absence of further chemical-specific information, the EPA and MADEP guidance instructed risk assessors to assign the B[a]P slope factor to all PAHs considered to be carcinogenic. This approach was considered to be protective of public health as benzo[a]pyrene is thought to be one of the most potent carcinogens among the PAH's. In 1993, USEPA formally adopted provisional guidance for estimating cancer risks associated with polycyclic aromatic hydrocarbons (USEPA, 1993). The procedure uses information from the scientific literature to estimate the carcinogenic potency of several PAHs relative to benz[a]pyrene. These **relative potencies** may be used to modify the CSF developed for benzo[a]pyrene for each PAH, or to calculate B[a]P-equivalent concentrations for each of the PAH's (which would then be used with the B[a]P slope factor). The latter approach is similar to that used for the evaluation of dioxins.

The relative potency values published by the USEPA and others (Chu and Chen, 1984; Clement, 1988; Nisbet and LaGoy, 1992) are being reviewed and may be adopted (perhaps in a modified form) by MA DEP Office of Research and Standards. A list of the USEPA relative potency values is presented in Table 7.4 for use in c.21E risk characterizations pending publication of MADEP recommended values (which will be available through the MA DEP Bulletin Board System).

Figure 7.1



### PAH Noncancer Risk:

While the USEPA has published (in *IRIS* and *HEAST*) threshold effects toxicity information for a number of polycyclic aromatic hydrocarbons, for many other members of this chemical family such information has not yet been developed. In order to adequately characterize the noncancer risks associated with these PAHs, MADEP recommends that the published reference dose, reference concentration, or analogous value for a structurally similar PAH be adopted for each compound for

which sufficient chemical-specific toxicological information is unavailable.

Examples of how the potential toxicity of individual PAHs may be evaluated are described in Example 7.2.

### 7.2.4.3 Polychlorinated Biphenyls (PCBs).

Polychlorinated biphenyls (PCBs) is the name given to the general class of compounds in which one or more chlorine atoms are bonded to a biphenyl structure (Figure 7.2). The PCB family is comprised of 209 different variants, or **congeners**, depending upon the number of chlorine atoms present and their position on the biphenyl structure. PCBs may also be described according to *isomeric groups*, which are families of PCBs having the same number of chlorine atoms and thus the same molecular weight. For example, 2,2'-Dichlorobiphenyl is one of 209 chlorinated biphenyl congeners and one of 12 possible dichlorobiphenyls; these 12 dichlorobiphenyls are considered **isomers** of each other.

PCBs are typically found in the environment as mixtures of different PCB congeners. These mixtures (also known as *Aroclors*, a trade name of the Monsanto Corporation) are identified by a four digit numbering code in which the first two digits (12) indicate that the parent molecule (the biphenyl) has twelve carbon atoms, and the last two digits indicate the percent chlorine by weight. Thus, Aroclor 1260 is a chlorinated biphenyl mixture with an average chlorine content of 60%. [The only exception to this nomenclature is Aroclor 1016, which retains the name by which it was known during development. Aroclor 1016 is a mixture which has an average chlorine percentage of 41.5%, making it very similar

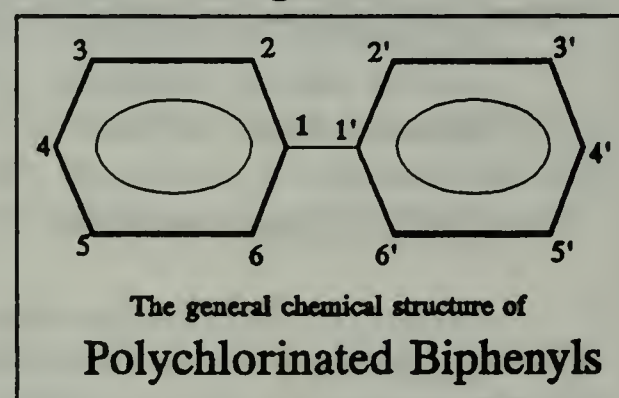
Table 7.4

#### Relative Potency Values for Individual PAH's: (USEPA, 1993)

Compound	Relative Potency Factor
Acenaphthene .....	NA
Acenaphthylene .....	NA
Anthracene .....	NA
Benz(a)anthracene .....	0.1
Benz(a)pyrene .....	1
Benzo(b)fluoranthene .....	0.1
Benzo(g,h,i)perylene .....	NA
Benzo(k)fluoranthene .....	0.01
Chrysene .....	0.01
Dibenz(a,h)anthracene .....	1
Fluoranthene .....	NA
Fluorene .....	NA
Indeno(1,2,3-cd)pyrene .....	0.1
2-Methylnaphthalene .....	NA
Naphthalene .....	NA
Phenanthrene .....	NA
Pyrene .....	NA

NA - Chemical is not currently considered to be carcinogenic by USEPA so no relative potency value is currently applicable.

Figure 7.2



## Example 7.2

### EVALUATION OF POLYCYCLIC AROMATIC HYDROCARBONS (PAH's)

#### Cancer Risk

A polycyclic aromatic hydrocarbon for which a cancer slope factor has not been developed by USEPA may be evaluated using the relative potency values recommended by USEPA (Table 7.4). These values can be used in one of two ways which are mathematically equivalent. To illustrate, let's assume that Indeno[1,2,3-cd]pyrene was reported at a disposal site at a concentration of 2 mg/kg.

- In the first approach, the relative potency factor for indeno[1,2,3-cd]pyrene (0.1, from Table 7.4) is used to estimate a cancer slope factor for this compound by adjusting the slope factor for benzo[a]pyrene (7.3 mg/kg/day, from USEPA IRIS, 1993):

$$CSF_{i[1,2,3-cd]p} = 0.1 \times 7.3 \text{ (mg/kg/day)}^{-1} = 0.73 \text{ (mg/kg/day)}^{-1}$$

- The second approach would be to adjust the concentration of indeno[1,2,3-cd]pyrene (2 mg/kg, in this example) by the relative potency value (0.1, from Table 7.4) to estimate a benzo[a]pyrene equivalent concentration, to which the B[a]P slope factor would be applied:

$$B[a]P_{\text{equiv. conc.}} = 0.1 \times 2 \text{ mg/kg} = 0.2 \text{ mg/kg}$$

#### Noncancer Risk

A polycyclic aromatic hydrocarbon for which a reference dose (RfD) has not been developed by USEPA may be evaluated using a reference dose from a structurally similar PAH. Using the example above, indeno[1,2,3-cd]pyrene (for which there is currently no RfD) is structurally similar to fluoranthene: both chemicals have a 5-carbon ring structure bound to three aromatic rings, although indeno[1,2,3-cd]pyrene has two additional aromatic rings (see Figure 7.1). The reference dose for fluoranthene is 0.04 mg/kg/day (USEPA IRIS, 1993). This value would be adopted to evaluate potential noncancer risks associated with indeno[1,2,3-cd]pyrene.

to Aroclor 1242.] It is important to note that an Aroclor mixture may contain dozens of individual PCB congeners representing several isomeric groups.

As described earlier in this section, MADEP relies heavily upon the work of the USEPA and its published collection of agency-reviewed toxicity information published primarily in the *Integrated Risk Information System* (IRIS) and the *Health Effects Assessment Summary Tables* (HEAST). While it is generally unnecessary to duplicate the USEPA's efforts in developing toxicity information, the DEP Office of Research and Standards has staff toxicologists to fill data gaps or review supplemental information. The following is a summary of MADEP's general approach to the selection of toxicity information:

- ▶ When it exists, MADEP recommends the use of USEPA toxicity information from *IRIS* or *HEAST* for a given chemical.
- ▶ For *mixtures* of chemicals, the USEPA may publish toxicity information for the mixture as a whole or for *some* constituents of the mixture. When information is only available for certain formulations of a mixture, or for a limited number of constituents of a mixture, MADEP must, *as a matter of science policy*, determine how the limited information should be extrapolated to (a) other formulations of the mixture, or (b) the mixture as a whole.

For the evaluation of polychlorinated biphenyls, MADEP has specific policies based upon the information available at the time that this document was prepared. The reader is urged to consult the MADEP Office of Research and Standards or the MADEP Risk Assessment Bulletin Board for the current status of this information. The MADEP/ORS recommends the following:

- ▶ the use of the USEPA derived CSF of  $7.7 \text{ (mg/kg/day)}^{-1}$  for all PCB mixtures. *"Although it is known that PCB congeners vary greatly as to their potency in producing biological effects, for purposes of this carcinogenicity assessment, Aroclor 1260 is intended to be representative of all PCB mixtures."* (USEPA *IRIS* file for PCBs, 1993)
- ▶ the use of the Aroclor-specific USEPA derived chronic, oral reference dose of  $7 \times 10^{-5} \text{ mg/kg/day}$  for Aroclor 1016 (USEPA *IRIS* file for Aroclor 1016, 1993). This value may also be applicable to PCB mixtures containing similarly chlorinated congeners, such as Aroclor 1242.
- ▶ the use of the Aroclor-specific USEPA derived chronic, oral reference dose of  $2 \times 10^{-5} \text{ mg/kg/day}$  for Aroclor 1254 (USEPA *IRIS* file for Aroclor 1254, 1994). This value may also be applicable to PCB mixtures containing similarly chlorinated congeners, such as Aroclor 1260.
- ▶ the use of other Aroclor-specific USEPA derived values, as they become available.

#### 7.2.4.4 Total Petroleum Hydrocarbons.

The Total Petroleum Hydrocarbon (TPH) measure often reported for c.21E disposal sites is generally considered inadequate for the purposes of site specific risk assessment. The commonly used infra-red (IR) analysis technique does not identify individual compounds or related groups of constituents. The mixture of petroleum hydrocarbons reported as the TPH parameter includes a wide range of compounds of different toxicities. Thus, the health effects (or the risk of such effects) associated with exposure to particular concentrations of "TPH" cannot be determined.

The MADEP Bureau of Waste Site Cleanup is developing a "*Policy for the Investigation, Assessment and Remediation of Petroleum Releases*" (or the Petroleum Policy) which will include a section entitled "*Interim Final Petroleum Report: Development of a Health Based Alternative to the TPH Parameter.*" That document identifies an alternative to the TPH parameter which can be used to conduct site-specific risk assessments and the document will propose dose-response values to be used with the specified analytical parameters. The key element of the policy is that the proposed analytical technique would allow the quantification of several ranges of compounds (rather than a single TPH result) and each range would be assigned a "reference compound" whose toxicity would be representative for all chemicals in that range.

The interim final report, *Development of a Risk Based Alternative to the TPH Parameter* (MADEP, 1994a) is currently available through the MA DEP Bulletin Board and the State Bookstore.

### **7.2.5 Recommended Format**

Tables 7.5 and 7.6 present recommended formats for presentation of dose-response information for threshold and nonthreshold effects, respectively.

For threshold effects, separate tables should be presented for chronic and subchronic effects. Information that should be presented in the table includes:

- Name
- Toxicity value
- Source of toxicity value (i.e IRIS, HEAST)
- Date that the toxicity value was last verified
- Study Type - how the OHM was administered
- Confidence Level - identified by USEPA
- Critical Effect - target organ and toxic effect on which the dose-response value is based
- Test Animal - animal species on which the study is based
- Uncertainty of modifying factors - factors listed by agency generating the toxicity value

For nonthreshold effects, the information that should be presented in the table includes:

- Name
- Potency Value or Unit Risk
- Source of toxicity value (i.e IRIS, HEAST)
- Date that the toxicity value was last verified
- Study Type - how the OHM was administered
- Weight of Evidence - USEPA weight of evidence classification
- Test Animal - animal species on which the study is based
- Cancer type - tumor type listed by the agency establishing the toxicity value

### 7.3 EXPOSURE ASSESSMENT - CONCEPTS

The exposure assessment is a critical component of the site assessment process as it describes, both qualitatively and quantitatively, the contact between the contamination and the people who are potentially affected by the contamination. The exposure assessment must be consistent with the primary questions asked in the risk characterization process:

*Given the current and identified foreseeable uses of the site, would the oil or hazardous material present pose significant risk of harm to health, safety, public welfare or environment if no further remedial action were to occur?*

or

*If a proposed remedial alternative is implemented and meets its identified remediation goals, will a condition of no significant risk of harm to health, safety, public welfare and the environment be achieved given the current and identified foreseeable uses of the site?*

Whether the risk characterization is a **baseline** assessment (which answers the first question) or an evaluation of a proposed remedial alternative, the exposure assessment must incorporate site conditions associated with both current use and identified foreseeable uses of the site and surrounding environment. In this context site use or site activity are shorthand references for the exposures to site contaminants which could occur at or near the disposal site.

There are two important results of the exposure assessment: exposure profiles and quantitative estimates of exposure. An exposure profile is a narrative description of the exposures which may occur at the disposal site, and the information is often summarized in one or more tables for easy reference. The quantification of exposure translates the narrative exposure profile into a series of exposure equations resulting in numerical estimates of exposure. These numerical estimates are subsequently used in the risk calculations.

EXAMPLES: Dose-Response Summary Tables

Table 7.2.5

Chronic Oral Reference Doses									
Chemical Name	CAS Number	Chronic Oral RfD	Source	Date Last Verified	Study Type	Confidence Level	Target Organ/ Critical Effect	Test Animal	Uncertainty/M odifying Factors
Carbon Tetrachloride	56-23-5	7E-04	IRIS	1/94	Gavage, 12 weeks	Medium	Liver/Lesions	Rat	1,000
c-1,2-Dichloroethylene	156-59-2	1E-02	HEAST	1/94	Gavage, 90 day	N/A	Blood/Decreased Hematocrit	Rat	3,000
Dichloromethane	75-09-2	6E-02	IRIS	1/94	Drinking Water, 2-year	Medium	Liver/Liver Toxicity	Rat	100

Table 7.2.6

Oral Cancer Slope Factors								
Chemical Name	CAS Number	Oral CSF	Source	Date Last Verified	Study Type	Weight of Evidence	Tumor Type	Test Animal(s)
Carbon Tetrachloride	56-23-5	1.3E-01	IRIS	1/94	Gavage	B2	Hepatocellular carcinomas/hepatomas	Hamster Mouse Mouse Rat
p-Cloronitrobenzene	100-00-5	1.8E-02	HEAST	1/94	Diet	B2	Cardiovascular System Tumors	Mouse
Dichloromethane	75-09-2	7.5E-03	IRIS	1/94	Inhalation Drinking Water	B2	Hepatocellular adenomas or carcinomas Hepatocellular cancer and neoplastic nodules	Mouse Mouse

## Baseline Risk Characterizations

*Baseline risk characterizations* evaluate the "**no action**" alternative: What risks would be posed by the contamination if no remedial action were taken? If risk reduction measures have already been completed, then the baseline risk characterization would evaluate the risks if no further remedial action were taken.

Anticipated or proposed remedial actions or land use restrictions should never be incorporated into a baseline risk characterization, as it would no longer be an evaluation of the "no action" alternative. By extension, completed Immediate Response Actions (IRS's), Release Abatement Measures (RAM's) or Utility-related Abatement Measures (URAM's) can be considered in a baseline risk characterization *only if they are considered to be permanent*.

For example, temporary fencing of an area as an Immediate Response Action to eliminate direct contact with contaminated soils should not be incorporated into a baseline risk characterization. Rather, the conditions which would exist in the absence of the IRA should be evaluated to determine the need for a permanent solution: the exposure assessment would assume that no fence is in place. If, however, a completed IRA, RAM or URAM permanently changes the exposure potential at a disposal site (e.g., the complete removal and disposal of contaminated soil), that impact of that permanent response action would be considered in the baseline assessment.

### 7.3.1 Development of Exposure Profiles

Exposure profiles provide the narrative description of how exposure takes place at the disposal site. The exposure profiles assist the risk assessor in identifying appropriate values for the exposure variables (such as intake rate, frequency of exposure, etc...) by providing a context within which the variables have meaning. Exposure profiles are sometimes referred to as "*exposure scenarios*".

An exposure profile should be developed for each of the receptors identified for all current and foreseeable uses of the site. The number and content of the exposure profiles will vary from site-to-site, reflecting the nature and complexity of the exposures which may occur.

There are also several ways to streamline this process and minimize the number of exposure profiles needed. If the current use of the site is assumed to remain unchanged into the future, then separate exposure profiles need not be developed for both the current and future receptors. For example, if a residential area is being evaluated and the land is likely to remain residential, it is unnecessary to construct exposure profiles to represent other uses. For a property where the frequency and intensity of exposure is low, it is also possible to assume that the use and activities will remain the same, but

this assumption requires an activity and use limitation, as detailed in Section 2.1 of this Guidance Document.

Another situation conducive to streamlining exposure profiles is when two (or more) hypothetical receptors share the same exposures but the magnitude of exposure is demonstrably greater for one. In this case, a detailed exposure profile may be developed for the highly exposed receptor, accompanied by the conclusion that lesser exposed receptors will also be protected.

The USEPA Guidelines for Exposure Assessment (1992) describes exposure scenarios (exposure profiles) as containing the "*facts, data, assumptions, inferences, and sometimes professional judgement*" about how the exposures take place. Since these factors determine the magnitude of exposure (and thus the magnitude of the risk posed by the disposal site) it is important that there be a clear description and summary of this information. The exposure profiles allow anyone concerned about the disposal site to read and understand what was considered in the risk characterization and what was the basis for the decision on the need for remedial action.

Note that the information which goes into an exposure profile (the receptors, exposure points, exposure point concentrations, etc...) comes from the site investigation. Thus the investigation must be designed in such a way to provide the risk assessor with information suitable for the risk characterization. These exposure attributes are interrelated (e.g., the location of the exposure points depends on the migration of the OHM and the activities of the receptors) so the information should be collected and processed in an iterative manner. The following subsections discuss the specific information which must be gathered for the risk characterization, presented in the site assessment report or the documentation of the risk characterization and summarized in the exposure profiles.

#### Risk Characterizations for Remedial Alternatives

A risk characterization for a remedial alternative is performed to determine whether that action will achieve (if the alternative is *proposed*) or has achieved (if the alternative has been *implemented*) a condition of No Significant Risk.

The conclusions of the risk characterization report must be explicit about the conditions and assumptions upon which the risk characterization is based. Sections 40.0923(4) and (5) of the MCP require that such conditions and assumptions (such as *Activity and Use Limitations*, or the implementation of a remedial measure) be clearly and concisely stated and it must be noted that the results of the risk characterization are only valid upon if and when the remedial measures (including AULs) are carried out.

### 7.3.1.1 Site Information Required to Quantify Exposures

The exposure assessment begins with a description of the physical characteristics of the disposal site. This information is typically collected as part of a Phase I (310 CMR 40.0480) or Phase II (310 CMR 40.830) site investigation, although the type of information needed and the appropriate level of detail should reflect the nature and complexity of the site as well as point in time at which the risk characterization is being performed. Relevant site information would include:

- the address and location of the disposal site;
- a detailed map of the site and surrounding area;
- a description of the land uses at and surrounding the disposal site;
- a listing and description of natural resources and vegetation at or near the disposal site (e.g., surface waters, wetlands, forests, grassy areas, etc...);
- a summary of the use of oil or hazardous material and a description of any known and relevant releases which may have occurred;
- a summary of site hydrogeological characteristics, including depth to groundwater, direction and rate of flow, soil types, etc...
- a summary of background concentrations of oil or hazardous materials

Some of this information may be available through the Massachusetts Geographic Information System (MASS-GIS) which provides color plots or digital data of wetland areas, sole source aquifers, endangered species habitats and other natural resource areas. Several data packages have been developed specific to c.21E site investigations. For a full

#### **WHO ?...WHAT ?...WHEN ?...WHERE ?...HOW ?**

The Exposure Profile should contain information to completely describe each receptor's exposures to oil or hazardous material at the disposal site.

- Who is exposed? The exposure profile should be developed for each receptor likely to be present at the disposal site or in the surrounding environment, and who, as a result, would likely be exposed to OHM.
- Where does the exposure occur? Is the contamination limited to the area near the original source, or has/will migration of contaminants result in potential exposures at a more distant point?
- What are the receptors exposed to? What oil or hazardous materials are present at the disposal site? What concentrations of the material have been reported?
- When does the exposure occur? Are the exposures likely under current site conditions, or will the exposure be of concern if the site use changes in the future?
- How does exposure occur, and how often? What receptor actions or activities result in contact with the oil or hazardous material? Do these events happen every day or are they rare incidents?

listing of available data, contact MassGIS, EOE Data Center, 20 Somerset Street, Boston, MA 02108, (617) 727-3888.

### 7.3.1.2 Identification of Potential Human Receptors

Section 40.0921 of the Massachusetts Contingency Plan contains regulations specific to the identification of receptors at c.21E sites.

The documentation of the risk characterization should contain a description of the potentially exposed persons who live, work, play, visit, or otherwise come to the disposal site or the surrounding environment. In identifying these receptors, the risk assessor must consider not only those people currently associated with the disposal site, but also those who may frequent the site in the future if the use of the site were to change (See the discussion on Current and Foreseeable Use, Section 2.1).

The human receptors are described as subpopulations (subsets of the more diverse overall population of Massachusetts) rather than specific individuals so that the results of the risk characterization can be generalized. For example "*children*", a specific, identifiable group within the larger general population of humans, are often identified as receptors of concern at c.21E disposal sites. (Hypothetically a risk assessor could identify a specific (real) child who lives at the site and conduct a risk assessment based upon that child's physical characteristics and behavioral patterns, but the result of such an assessment would be valid only for that child and could not be generalized to other children who may visit the site or live there in the future.) Note, though, that while the receptors are described in terms of "subpopulations" or "subgroups", the product of the risk assessment is still an estimate of the risk that applies to the protection of an individual within that group. The MCP focuses on individual risk, not population risk.

The receptor groups are described in terms that highlight their relationship to the site and the unique characteristics of the subpopulation. For example, the term *site residents* describes a diverse group which lives (or may in the future live) at the disposal site. For the purposes of the risk characterization the site residents should be further divided into subpopulations based upon gender and age if those factors are indicative of a higher exposure potential or greater susceptibility to environmental contamination. Young children and women of child-bearing age are often chosen as receptors of concern in residential locations because of these factors. At industrial locations, adults may be the most susceptible receptors. Identification of the most sensitive subpopulation should be done on a site by site basis.

### Example 7.3

EXAMPLE RECEPTOR: Site Resident		
Exposure of Concern/ Health Endpoint	Typical Subpopulation(s) Evaluated	Discussion
Acute Exposure, Noncancer Effects	2 year old child 22 year old woman	The young child is of concern for acute exposures (typically 1 event or several exposures over a short period of time) due to the higher exposure potential while potential developmental effects could be of concern for the woman of child-bearing age.
Subchronic Exposure, Noncancer Effects	2 year old child 22 year old woman	The young child is of concern for subchronic exposures (typically 2 weeks to a year) due to the higher exposure potential while potential developmental effects could be of concern for the woman of child-bearing age.
Chronic Exposures, Noncancer Effects	1-8 year old child	A young child would typically experience the highest exposure in a residential setting. Chronic exposures to adults would not have to be specifically evaluated for noncancer health effects unless the adult is assumed to take part in activities which would result in unusually high exposures.
Chronic Exposures, Cancer Risk	Resident 1-31 years old	Since the magnitude of the cancer risk is dependent upon the total amount of material contacted, a 30 year exposure which incorporates the age groups which experience the highest rates of exposure should be evaluated.

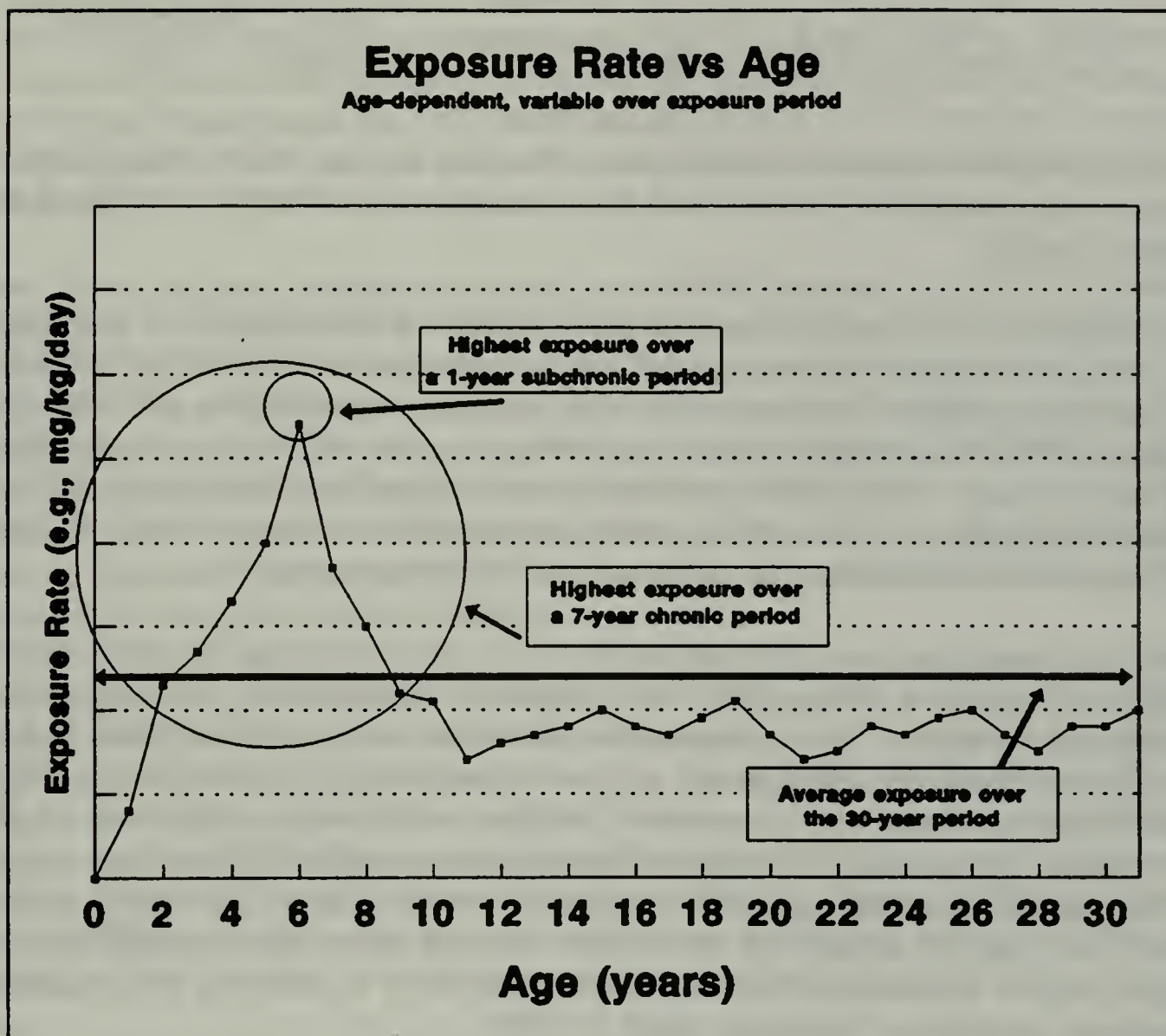
Thus to adequately evaluate the "site residents" the risk assessor may need to look at several specific receptors to insure that all sensitive subpopulations are being protected. Example 7.3 describes typical receptors who might be chosen to evaluate a residential exposure scenario.

By focusing on the subpopulations experiencing the highest rates of exposure the risk assessor may conclude that all other subpopulations at the location would be subject to lower exposures and risks than those calculated. Figure 7.3 illustrates how exposure may vary by age and highlights periods of high exposure which may need to be evaluated by the risk assessor.

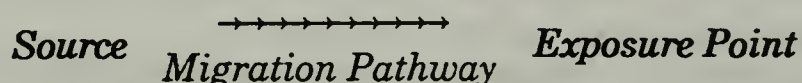
#### 7.3.1.3 Identification of Exposure Points

For receptors to be exposed to a contaminant at or from a disposal site, a realistic pathway must be established leading from the source of the oil or hazardous material to the receptor. The point at which the contact occurs is referred to as the *exposure point* (or "exposure setting"). Potential exposure points must be identified per 310 CMR 40.0924. The route by which the material travels from the source to the exposure point is called the *migration pathway*.

Figure 7.3



The migration pathway describes the movement of the material, and it is comprised of three parts: a release *source*, a release *mechanism*, and a release (or transport) *medium*. The documentation of the risk characterization must describe the source of the OHM, how the material was released to the environment and its movement through the environment. This information is routinely gathered during site investigations (see 310 CMR 40.0904), but it is restated here in terms used by risk assessors. A simple example of a migration pathway would be the volatilization of a chemical from a drum to indoor air, where the source of the OHM is the drum, the release mechanism is volatilization, and the transport medium is the air. A migration pathway may include several transport media.





Potential points of exposure may be distant from the original source material, so the risk assessor must consider the current and future migration pathways to identify all potential exposure points.

The regulations also require that *hot spots* (Section 2.2) be identified as separate and distinct exposure points for purposes of risk characterization (310 CMR 40.0924(2)). This requirement ensures that areas with high relative contamination will not simply be averaged into a wider area of lesser contamination, thus minimizing (or diluting) their potential impacts. (The MCP describes a number of risk reduction tools (IRAs, RAMs, URAMs) which can and should be used to address hot spots in a timely fashion, thus reducing overall site risks in an efficient, cost-effective manner.)

While the regulations and guidance use the term *exposure point*, the term may actually describe an area of a disposal site or surrounding environment and not necessarily a single, discrete point. The exposure point should be an area within which the receptor has an equal likelihood of exposure, such as "a backyard" or "a schoolyard". If there are areas within the site which receptors frequent at a higher rate (such as the area surrounding playground equipment within a larger schoolyard) then those areas should be evaluated as separate and distinct exposure points. Figure 7.4 depicts a site within which there are two areas that should be evaluated separately (in addition to the area of generalized contamination) as exposure points: a hot spot and a playground. Additional examples of exposure points include:

- an area where people come into contact with contaminated soil,
- a drinking water well or a potential drinking water well location
- a building into which air contaminants are migrating and accumulating in the indoor air
- an area in which ambient air contains elevated levels of site-related contaminants

In general, an exposure point for soil, sediment or surface water should be delineated by the distribution of oil or hazardous material in the environmental medium. For example, for soil, an exposure point should be a contaminated area within which the exposure of concern is likely. The area outside the boundaries of the contamination should not be included in the exposure point, and data from those areas should not be included in the concentration estimate. There are two reasons for this recommendation:

- 1) There is rarely enough information on current small-scale exposure patterns in the vicinity of a contaminated area, for example a residential yard, to justify assumptions about the relative amount of time spent in the area known to be contaminated.

- 2) The full areal extent of contamination is not always known, unfortunately, at the time of the risk characterization. Sample collection is often focused on the areas where contamination is expected and/or obvious, and other areas are not fully characterized (although those areas may be contaminated as well). The practice of treating the contaminated area as the entire exposure provides a conservative estimate of exposure.

There may be some situations where the default approach described above is not appropriate. In cases where the extent of soil contamination is well defined and clearly constitutes only a fraction of the area over which the receptor group of concern is equally likely to be exposed, the exposure point may be an area that is somewhat larger than the contaminated area. The best example of a situation where this exception might be applied is a residential back yard. If a resident is equally likely to contact the soil at any locations within the yard, and if the contaminated area has been clearly delineated and found to comprise only a fraction of the yard, the risk assessor may opt to define the entire backyard as the exposure point.

When considering whether the exposure point should cover an area larger than that which is contaminated, the scale of the contaminated area relative to the anticipated exposure pattern is an important consideration. For example, consider a vacant lot where children are likely to play. If  $\frac{1}{4}$  of a 2000 ft<sup>2</sup> lot were contaminated, it may be reasonable to assume that activity levels and exposures in the 500 ft<sup>2</sup> contaminated area are not likely to be any higher than those in the rest of the lot. However, if the  $\frac{1}{4}$  of a one acre lot is contaminated, it would be more difficult to justify the assumption that activity levels in the  $\frac{1}{4}$  acre that is contaminated will never be higher than in the surrounding area.

Another important consideration is whether the foreseeable activities are likely to result in more intense or more frequent exposures in some areas than in others. For example, in play parks, exposure intensity at any location depends upon the landscaping, the pattern of open space and the layout of equipment. If a small area of surface soil located within a large park were contaminated, the risk assessor may not be able to rule out the possibility that exposures to individual children will not be higher in that area than in other areas of the park. Therefore it would be more appropriate to designate the contaminated area alone as the exposure point, and not the entire park.

The burden to demonstrate that the designation of an exposure point is appropriate and conforms with this guidance rests with the risk assessor. The documentation of the risk characterization should present summary tables describing the migration pathways identified and the exposure points to be evaluated.

#### 7.3.1.4 Identification of Exposure Routes

The mechanism by which a receptor comes into contact with the oil or hazardous material is called the Exposure Route. Typical exposure routes described at c.21E disposal sites include:

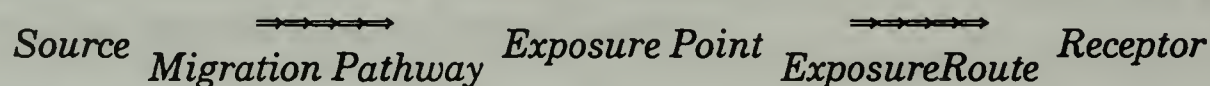
- **INGESTION** of contaminated soil, water or food
- **INHALATION** of contaminated air or fugitive dust
- **DERMAL ABSORPTION** from contaminated water, soil or sediments

Remember that a receptor may be exposed to oil or hazardous material at one *or more* exposure points, and that at each exposure point the receptor may be exposed via one *or more* routes. The exposure profile for the receptor should describe such multiple exposure scenarios in a way which makes clear to the reader that the combination of exposures to the receptor is being addressed in the risk assessment.

#### 7.3.2.5 Identification of Exposure Pathways

The *Exposure Pathway* is the term used to describe the course that the oil or hazardous material takes from the source of the material to the receptor of concern. The term encompasses the source, the migration pathway, the exposure point, the receptor and the exposure route.

#### Exposure Pathway:



Thus the Exposure Profile (or exposure scenario) developed for each receptor would describe, in narrative and tabular form, the circumstances under which the receptor is exposed. The exposure profile may be relatively simple if a single receptor group is exposed at one location via one route of exposure. Exposures at c.21E sites are generally a bit more complex, however. A receptor group may be exposed to the oil or hazardous material through a number of exposure routes at several locations. Figure 7.5 illustrates a situation in which there is one receptor, one source of OHM, a migration pathway and four exposure routes. (There are also four exposure pathways, as there are four routes by which chemicals may move from the source to the receptor.) Example 7.4 demonstrates how a more complex example may be clearly presented in a tabular format.

### 7.3.2 Basic Approach/Assumptions

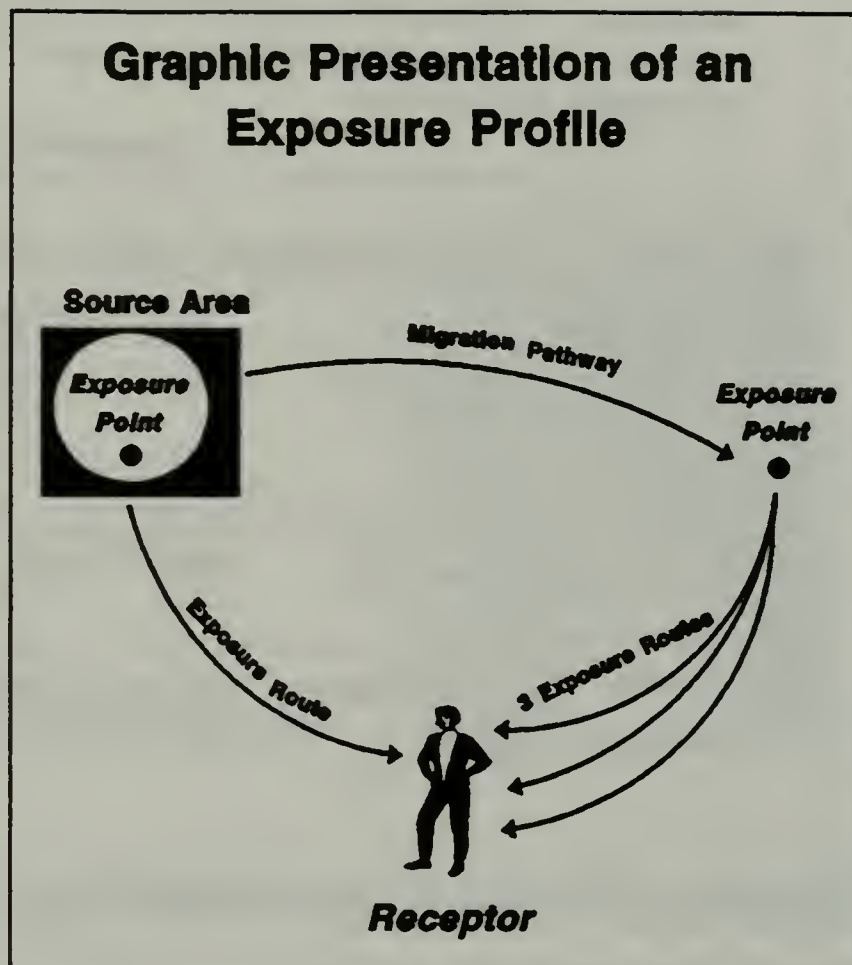
The basic approach which should be taken in an exposure assessment under the MCP is to produce an assessment which is realistic and health protective. The regulations (310 CMR 40.0992(2)) stipulate that the objective of a Method 3 risk characterization is to provide a conservative estimate of the impact that the oil and/or hazardous material may have on the receptors at the site and in the surrounding environment. The assessment should not be a "worst case" exposure assessment unless there are site-specific justifications for performing such an evaluation. (Worst case assessments are useful screening tools which may demonstrate that risks are clearly insignificant, but they are not useful in determining whether realistic risks are actually significant.)

Conversely, the assessment should not represent an "average case" which may underestimate potential risks experienced by a large portion of the exposed subpopulation, and thus would not be considered to be health protective. This section presents guidance on identifying receptor groups that are likely to be most susceptible to contamination at the site, and on selecting exposure parameters that will result in an appropriately conservative estimate of risk to that receptor group.

Numerous attempts have been made to define a combination of exposure assumptions which would result in a reasonable yet health-protective exposure assessment. USEPA (1989) defined a **Reasonable Maximum Exposure (RME)** as "the maximum exposure that is reasonably expected to occur at a site" and recommended specific exposure factors (USEPA, 1991) to be used to evaluate the RME. More recently (USEPA, 1992) the concept of "high-end" exposure, dose and risk estimates has been introduced:

*The high-end risk is taken to be a plausible estimate of the risk for persons at the upper end of the risk distribution. The intent of the high-end descriptor is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, high-end risk means risks beyond the 90<sup>th</sup>*

Figure 7.5



percentile of the population distribution, but not higher than the individual in the population who has the highest risk. The descriptor is intended to estimate the risks that are expected to occur in small but definable high-end segments of the subject population. The use of "above the 90<sup>th</sup> percentile" in the definition is not meant to precisely define the range of this descriptor, but rather to clarify what is meant conceptually by high-end.

#### Example 7.4

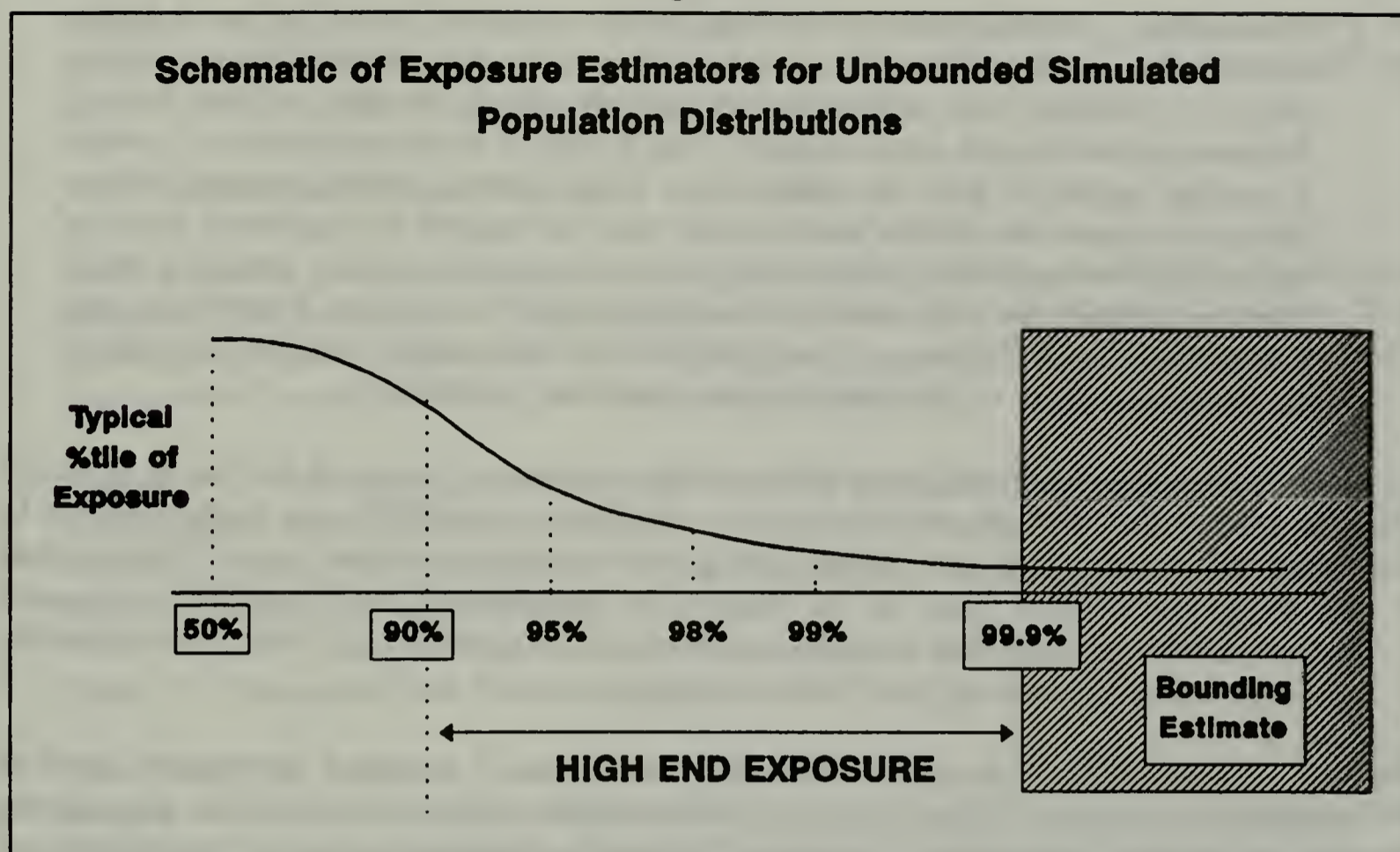
Exposure Profile Summary Table			
Receptor	Age	Exposure Point	Exposure Route
Resident	Young Child, age 1-6	Residential Backyard	Soil Dermal Contact
			Soil Ingestion
			Inhalation of Volatilized Material
			Ingestion of Groundwater
		School Playground	Soil Dermal Contact
			Soil Ingestion
	Older Child and Adult, age 7 - 30	Residential Backyard	Inhalation of Fugitive Dust
			Soil Dermal Contact
			Soil Ingestion
			Inhalation of Volatilized Material
			Ingestion of Groundwater

Figure 7.5 graphically depicts the "high-end" exposure range (from USEPA, 1992) from a hypothetical distribution of site exposure for a specified subpopulation.

MADEP has in the past recommended (MADEP, 1992b) that the exposure assessments identify the average exposure for the Maximally Exposed Individual (MEI) of a specified receptor group. The term "*Maximally Exposed Individual*" is, therefore, a misnomer for that receptor of concern since the evaluation would focus on the average individual within this subpopulation.

For the purposes of Method 3 Risk Characterizations performed under the MCP, the receptor subpopulation of concern would be characterized by those individuals whose activities (described by the frequency and duration of the actions) represent a full and unrestricted use of the site (considering the current and foreseeable uses identified) and who are most susceptible to the contamination at the site. The quantitative exposure assessment should describe a conservative estimate of a representative individual within that subpopulation. (Note that the "*fullest use*" does not necessarily mean that the highest possible values for exposure frequency and duration should be used.)

Figure 7.5



The subpopulations or receptor groups evaluated in the quantitative risk assessment should represent the most susceptible individuals and groups of all of those who are exposed to contamination at the site in question. Higher susceptibility is used here to mean a higher probability of experiencing adverse impacts as a result of exposure. Susceptibility is determined by the combination of the intensity of exposure and the sensitivity to toxic effects combined. Examples of receptor groups that are often identified as the most susceptible subpopulations include those described below:

- In typical residential areas, children are usually considered among the most susceptible receptors because (1) their activities are likely to result in more intense exposures than those of adults, (2) they are believed to intake higher amounts of soil by incidental ingestion, and (3) all other things being equal, their lower body weights result in higher normalized doses. Note that the first two factors relate to higher exposure intensity, while the third translates to higher sensitivity, all of which combine to make children generally more susceptible than adults to the contamination.
- In typical industrial areas, adults who work at the site are often considered as one of the most susceptible subgroups because their exposure frequency is higher than for others who may be exposed on occasion.

- Occasionally, pregnant and/or nursing women may be identified as a highly susceptible subgroup. The effects of concern in these cases may be developmental effects on fetuses and babies, not necessarily effects on the mother herself. Fetuses are considered more sensitive than adults to some contaminants because a one-day exposure may be sufficient to cause adverse developmental effects. Babies are more susceptible because they may be exposed to significant levels of fat-soluble contaminants which may become concentrated in mother's milk. Because of their low body weight, a baby's exposure can lead to a relatively high normalized dose. Babies and young children are also more sensitive than adults to the toxic effects of some substances, metals in particular.

It is worth noting that, although we have often spoken in terms of the "most sensitive receptors", most of the factors that lead to a higher susceptibility are in fact related to exposure intensity, and not necessarily a greater sensitivity to the toxin. While higher sensitivity to a toxin may be an important consideration, it is seldom addressed quantitatively in health risk assessments, because the same toxicity values are generally (perhaps unfortunately) applied to all subgroups.

Exposure assessments should use mid-range estimates of exposure parameters, such as such as intake rates, contact rates and bodyweights, which are known to vary among individuals within the specified receptor group. The arithmetic mean of concentrations at exposure points are recommended (See Section 7.3.3.5) for use in the exposure calculations. Again, note that the values used for frequency and duration of exposure should reflect realistic values for receptors making the fullest use of the site or resource (given the current and future uses determined for the location) while considering climatic conditions in Massachusetts.

This mix of mid-range and conservative values is intended to produce realistic upper-end exposure estimates which will be protective of public health and produce risk estimates which will be valid for comparison to the MCP Cumulative Risk Limits. For exposure assessments performed using probabilistic techniques (such as Monte Carlo analysis) the MCP stipulates that the 95<sup>th</sup> percentile value of the resulting exposure distribution for the specified receptor subpopulation be used to calculate risk estimates.

For risk assessors attempting to meet the regulatory requirements of both the MADEP and the USEPA, the risk estimates calculated using the USEPA "high end" exposures would likely be equal to or higher than those estimates using the MADEP approach. Thus, cleanup decisions based upon such "high end" estimates (used with the MCP risk management criteria) are likely to meet the requirements of the MCP, even though the specific mix of exposure parameters used in the calculations will be different in the different programs.

Exposure estimates calculated as described herein are considered to be protective of public health in that they are not likely to be underestimates of the "true risk" for individuals in the specified receptor subpopulation.

### 7.3.3 Quantitative Estimations of Exposure

Once exposure profiles have been developed describing the contaminants of concern, exposure points, exposure point concentrations and the receptors of concern, the potential exposures experienced by the receptors are quantified. This information will then be used to estimate risk, as described in Section 7.4.

This section of the guidance describes (a) the differences between exposure and dose, (b) the different types of doses which may be employed in the risk assessment, (c) the common factors used to estimate exposure, and (d) the pathway-specific equations employed to quantify exposure.

#### 7.3.3.1 Concepts and Terminology

The concept of exposure is complex, and the numerical value calculated by the risk assessor will depend upon the nature of the exposure pathway under investigation, the duration of the exposure, and the health effects associated with the chemicals of concern.

The US EPA Exposure Assessment Group defines exposure as the amount of material in contact with an organism and available for absorption. The material which reaches the organism's absorption barrier (such as the skin, lung or gastrointestinal tract) is referred to as the applied dose, while the absorbed (or internal) dose is defined as the amount of material which actually crosses the organism's exchange boundary. [Note that exposure is often thought of as the "*potential dose*" and taken as an approximation of the applied dose, as it represents the amount which could be absorbed if it were 100% bioavailable. Figure 7.6 (adopted from USEPA, 1992) illustrates the differences in these terms for the dermal, respiratory, and oral routes of exposure.

The type of exposure or dose used to characterize risk will depend upon the exposure pathway under evaluation and the nature of the toxicity information available for each chemical:

- Typically *respiratory* exposures are evaluated using the exposure point concentration in combination with a published Reference Concentration or Unit Risk value.
- Oral and dermal exposures are typically evaluated by modifying the applied dose with a *Relative Absorption Factor* (RAF) to insure that the calculated exposure is comparable to the Reference Dose or Cancer Slope Factor employed. (See Section 7.2 for a discussion of RAFs.)

Where appropriate, the equations given in the following pages include a Relative Absorption Factor. Under certain conditions the quantitative estimate of exposure will in fact be an estimate of the applied dose (or exposure) rather than an absorbed dose. For simplicity, the term "average daily dose" is used to describe the product of an "average daily exposure" and a Relative Absorption Factor.

### 7.3.3.2 Types of Average Daily Doses

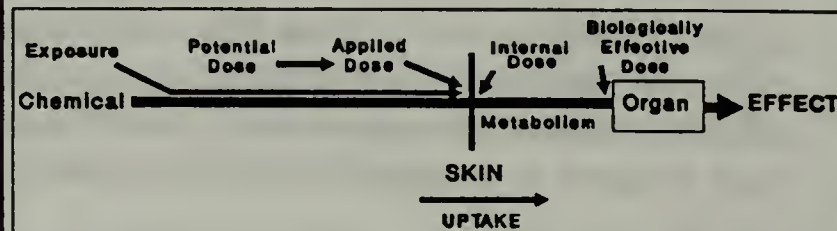
The equations presented below outline the procedure for the calculation of an Average Daily Dose of an oil or hazardous material. Depending upon the duration of the exposure under evaluation and the type of health effect (cancer or noncancer) of concern, the calculations may yield one of several results:

- **Lifetime Average Daily Dose (LADD):** A LADD in units of milligrams per kilogram body weight per day (mg/kg/day) should be calculated to estimate carcinogenic risk. The total intake during that exposure is normalized to a lifetime, taken to be 75 years. [Note that exposure may occur for all or some fraction of the receptor's lifetime.]
- **Chronic Average Daily Dose ( $ADD_{\text{chronic}}$ ):** Chronic human exposures are defined by MADEP to be those lasting seven years or more. The  $ADD_{\text{chronic}}$  (in units of mg/kg/day) is calculated for the characterization of potential noncancer risk resulting from long-term exposures, and the value must be an estimate of exposure experienced by the receptor *during the period of exposure*.
- **Subchronic Average Daily Dose ( $ADD_{\text{subchronic}}$ ):** Subchronic human exposures are defined by MADEP to be those lasting from several days up to seven years. The  $ADD_{\text{subchronic}}$  (in units of mg/kg/day) is calculated for the characterization of potential noncancer risk associated with such mid-range exposures, and the value must be an estimate of exposure experienced by the receptor *during the period of exposure*.

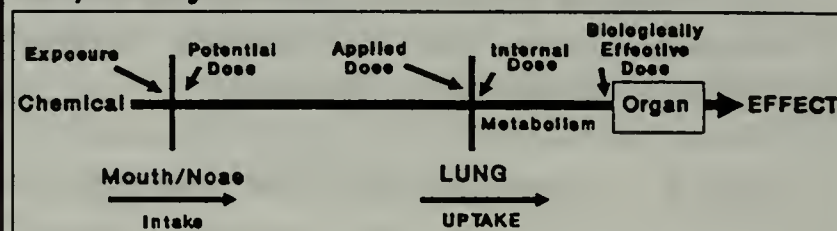
Figure 7.5

## Schematic of Dose and Exposure

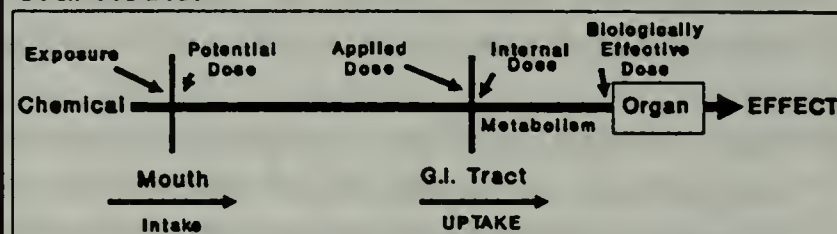
### Dermal Route:



### Respiratory Route:



### Oral Route:



- **Acute Average Daily Dose ( $ADD_{acute}$ ):** The Acute exposure may range from the instantaneous to those lasting up to several days, and the  $ADD_{acute}$  (in units of mg/kg/day) is calculated for the evaluation of potential noncancer risks resulting from such short-term exposures.

**Inhalation risks are characterized by calculating the exposure concentration rather than the dose.** Therefore, the terminology used for inhalation exposures differs from that used for ingestion and dermal exposures. To estimate carcinogenic risk from an inhalation exposure, the *Lifetime Average Daily Exposure (LADE)* (milligrams per cubic meter air per day) is calculated rather than the LADD. To estimate risks of non-cancer effects from inhalation exposures, the *Average Daily Exposure (ADE)* is calculated for chronic, subchronic and acute exposures rather than the ADD.

Note that it is often necessary to calculate several different daily doses of a chemical to a receptor in order to evaluate all relevant exposure scenarios. For chemicals which are considered carcinogenic, a lifetime average daily dose must be calculated as well as all appropriate average daily doses (*chronic, subchronic and/or acute*) for the evaluation of noncancer health risks. For noncarcinogens, all appropriate average daily doses (*chronic, subchronic and/or acute*) must be calculated.

### 7.3.3.3 General Form of Dose Equations

The general form of the equations to estimate average daily exposure (ADE) and average daily dose (ADD) is presented as:

$$ADE = \frac{(Total\ Amount\ of\ OHM\ Contacted)}{(Averaging\ Period)} \quad (7-3)$$

and

$$ADD = \frac{(Total\ Amount\ of\ OHM\ Contacted) * (Relative\ Absorption\ Factor)}{(Body\ Weight) * (Averaging\ Period)} \quad (7-4)$$

Note that "dose" is taken to be "exposure" normalized to the receptor's body weight and adjusted for absorption/bioavailability (as described in section 7.2.3).

At c.21E disposal sites it is common to have situations where a receptor may be exposed to a chemical through multiple exposure pathways, such as ingesting contaminated soil and absorbing the material following dermal contact with contaminated soil. In such cases, the doses of an oil or hazardous material received via different routes of exposure are assumed to be additive unless there is strong evidence otherwise.

$$\text{Cumulative Risk} = \sum \sum (\text{Chemical}_i, \text{Exposure Pathway}_i) \quad (7-5)$$

General equations for the calculation of Average Daily Dose are presented in this section for some frequently encountered exposure pathways. These equations are not intended to represent the universe of potential models and they must be tailored to site-specific conditions. It is expected that additional exposure pathways may be identified, and an average daily dose may be calculated, using appropriate models, for each receptor of concern.

There are a number of common exposure factors that are employed in virtually all of the exposure equations, and the discussion which follows describes some of the issues which may arise when using these elements. Exposure factors which are specific to a particular pathway are discussed in the subsection which presents the equations for that pathway.

The daily dose(s) of each OHM calculated for each potential receptor should be summarized in the risk characterization report in a manner which is clear and concise. Summary tables presenting the equations and the exposure assumptions used to calculate the daily dose should also be presented and well referenced.

#### **7.3.3.4 Descriptions of General Exposure Factors**

There are eight exposure factors which recur throughout the equations used to estimate the dose of oil or hazardous material experienced by a potential receptor:

- Chemical Concentration
- Body Weight
- Frequency of Exposure
- Duration of the Exposure Event
- Duration of the Exposure Period
- Relative Absorption Factor
- Averaging Period
- Units Conversion Factors

These factors are generally used in the same manner regardless of the exposure pathway under investigation, so it is useful to discuss them separately.

#### **Chemical Concentration**

The concentration of the oil or hazardous material used to quantify exposure is the Exposure Point Concentration, or EPC, described in section 7.3.4.5. The exposure point concentration is expressed in terms of mass of the material per unit mass (or

volume) of the exposure medium:  $\text{mg}_{\text{OHM}}/\text{kg}_{\text{soil}}$ ,  $\mu\text{g}_{\text{OHM}}/\text{liter}_{\text{water}}$ , and  $\mu\text{g}_{\text{OHM}}/\text{m}^3_{\text{air}}$ . When concentrations are expressed in terms of parts-per-million (ppm) or parts-per-billion (ppb), care must be taken to convert the concentrations to the appropriate units.

**Soil, sediment, food:**  $1 \text{ mg/kg} = 1 \mu\text{g/g} = 1 \text{ ppm}$   
 $1 \mu\text{g/kg} = 1 \text{ ppb}$

**Water:**  $1 \text{ mg/liter} = 1 \text{ ppm}$   
 $1 \mu\text{g/liter} = 1 \text{ ppb}$

**Air:**

$$1 \frac{\text{mg}}{\text{m}^3} = \frac{1 \text{ ppm} * \text{M.W.}}{22.4 * \frac{T}{273^\circ \text{K}} * \frac{P}{760 \text{ Torr}}} \quad (7-6)$$

Where T is the air temperature (often assumed to be 25° C or 298° K) and P is the atmospheric pressure (often assumed to be 1 atmosphere or 760 Torr), and M.W. is the molecular weight of the chemical under evaluation.

The exposure point concentration is represented in these exposure equations by the term:  $[\text{OHM}]_{\text{exposure medium}}$ . The exposure point concentration should not be adjusted for receptor exposure frequency, duration, etc... as those factors are generally addressed in the exposure calculations.

### Body Weight

A receptor's body weight is relevant throughout the dose equations as dose is expressed in terms of mass of contaminant per unit body weight per day (mg/kg/day). When each receptor of concern is identified, the receptor is often described in terms of occupation (resident, construction worker), age (a child age 1 to 6 years) and sometimes gender. The receptor's body weight is dependent upon its age and gender. Since body weight is easily measured, there are numerous summaries of age and gender-specific body weights. A table of such values used by ORS is included in Appendix B.

The receptor body weight (BW, typically expressed in kilograms, kg) must be matched to the age and gender identified in the exposure profile. Since exposure is often assumed to occur over a period of several years, the changes in body weight which might occur during the period of exposure must also be considered. (See section 7.3.3.6 for the mathematical treatment of age groups.)

Even within a given age/sex combination, there is some variability of body weight for that subpopulation: some 8 year old boys weigh more/less than other 8 year old boys.

This variation is well defined, and the distribution of body weights for this subpopulation of concern may be used as part of a probabilistic assessment of exposure. For evaluations requiring a point estimate of body weight, ORS recommends using the 50th percentile body weight for that subpopulation, unless there is strong evidence that the potentially exposed subpopulation is biased in some manner. Note that for a normal distribution, the 50th percentile approximates the arithmetic mean.

### **Frequency of Exposure and Duration of the Exposure Event**

A receptor may be exposed to oil or hazardous material continuously, at regular intervals, or in a sporadic manner. The Frequency of Exposure (EF) and the Duration of the Exposure Event (ED) in combination describe the pattern of exposure being modelled.

The frequency of exposure term describes how often the exposure event occurs over a given period of time. The term answers the questions: *How many times a day does exposure occur?*, *How many times per week?*, *per month?*, *per year?* Exposure Frequency may, in fact, be a string of terms which ultimately reduce to one expression:

$$\frac{1 \text{ event}}{\text{day}} * \frac{3 \text{ days}}{\text{week}} * \frac{4 \text{ weeks}}{\text{month}} * \frac{12 \text{ months}}{\text{year}} = \frac{144 \text{ events}}{\text{year}} \quad (7-7)$$

The Duration of the Exposure Event, as the name implies, describes how long each individual exposure event might last. The term is somewhat more complex than it sounds, however, because it must be consistent with the scale of the contact rate for the exposure being modelled. For some exposure pathways, the information available describing the contact rate is broken down to a small scale (such as hours). The respiratory pathway is perhaps the best example of this case as ventilation (breathing) rates are often measured and expressed in terms of cubic meters per hour, and breathing occurs throughout the day. For such exposures ED may be described as some number of hours/event. More common, however, are contact rates which are on the scale of days rather than hours. The ingestion pathway is typical of this case. While estimates have been published on the amount of water ingested during a *day*, there can be no reliable estimate of average *hourly* ingestion rates as drinking water is a sporadic event depending upon thirst and habit. For such exposures (including drinking water ingestion, soil ingestion and dermal contact) **ED is by definition 1 day/event**. During that "1 event" the receptor is assumed to receive the daily intake of the contaminant.

### Duration of the Exposure Period

The exposure period (EP) describes the length of time over which the receptor comes into contact with the oil or hazardous material. The exposure period depends upon the type of activities which lead a receptor to be exposed. Remember that the receptor may be exposed continuously, at regular intervals, or sporadically, depending upon the activity being modelled, so the exposure period would be the length of time between the first exposure experienced and the last. The EP term is typically expressed as some unit of time: days, months, years.

### Averaging Period

The equations which follow calculate *average* daily doses or *average* daily exposures, and the averaging period (AP) is the time (in days, months or years) over which the total intake is normalized.

Remember that a Lifetime Average Daily Dose (LADD) is calculated for the evaluation of *cancer risk*. While the duration of the exposure period (EP) might range from one day to an entire lifetime, the total intake during that exposure is normalized to 75 years (a lifetime). The averaging period is thus assigned a value of 75 years, and, for exposures lasting less than a lifetime, the values for EP and AP will be different.

For the evaluation of *noncancer risk*, however, the Average Daily Dose calculated should be representative of the exposure received while exposure is on-going (i.e., during the exposure period). Thus the duration of the exposure period (EP) and the averaging period (AP) for an chronic, subchronic or acute Average Daily Dose are variable factors depending upon the exposure being modelled, *but the AP is set equal to EP by definition*.

### Relative Absorption Factor

As described in the Dose-Response section of this guidance, the Relative Absorption Factor (RAF) relates the exposure and absorption estimated for the exposure pathway under evaluation to the exposure and absorption in the toxicological study on which the dose-response information is based. The RAF is dimensionless and is chemical and pathway specific.

### Units Conversion Factors

One of the most valuable habits a risk assessor can develop is to routinely conduct dimensional analyses on the equations used to quantify exposure. The exposure factors and analytical data used for a given calculation may come in several forms.

## EXPOSURE DURATION (EP) and AVERAGING PERIOD (AP)

The Averaging Period (AP) used in the equations to calculate dose will be equal to the Exposure Period (EP) for the evaluation of noncancer risks. When estimating cancer risk, AP is always equal to a lifetime (75 years) while EP may vary depending upon the exposure under investigation:

**Example:** The risk assessor is asked to evaluate the carcinogenic risk associated with a ten year exposure to chemical A. Estimation of carcinogenic risk requires the calculation of a Lifetime Average Daily Dose. Thus, the Averaging Period used for calculating the LADD would be 75 years while the Exposure Period would be equal to 10 years.

The risk assessor is also asked to evaluate the likelihood of non-carcinogenic health effects associated with that same ten year exposure. The assessor would calculate an Average Daily Dose Chronic ( $ADD_{\text{chronic}}$ ) where EP = 10 years and AP = 10 yrs.

For example, ventilation rates may be expressed as cubic meters per day or liters per hour; exposure point concentrations in drinking water may be in milligrams per liter or micrograms per liter. Dimensional analysis will reveal whether units conversion factors are necessary to insure that the result of the calculation (the dose) is expressed in the correct units (mg/kg/day).

Use of a units conversion factors (C) is equivalent to multiplication by one. The numerator and denominator of the factor must be an equivalent quantity expressed in different terms. It is not uncommon to need several conversion factors in the same equation to reconcile the dimensions of mass, volume and time.

EXAMPLES OF UNITS CONVERSION FACTORS (C)		
Relationship	The numerator and denominator may be reversed depending upon the form of the equation.	
1,000,000 mg = 1 kg	$C = 10^6 \text{ mg/kg}$	$C = 10^{-6} \text{ kg/mg}$
1 year = 365 days	$C = 365 \text{ d/yr}$	$C = 0.00274 \text{ yr/d}$
1,000 liters = 1 meter <sup>3</sup>	$C = 10^3 \text{ l/m}^3$	$C = 10^{-3} \text{ m}^3/\text{l}$

### 7.3.3.5 Estimating Exposure Point Concentrations - General Considerations

#### Sampling and Analysis

To assure that site sampling efforts provide adequate data for the risk assessment, the sampling and analysis plan should be developed in consultation with the risk assessor. Analytical data is collected during the site investigation to fully characterize the nature, extent, severity and horizontal and vertical distribution of the oil and hazardous materials at the disposal site. Some or all of the data obtained may be used for the risk assessment. The data obtained or selected for the risk assessment must be representative of actual and foreseeable exposures, and it must be compatible with the dose response value that will be used in the assessment.

#### Averaging

The exposure point concentration should represent the arithmetic mean of the concentrations to which an individual may be exposed over the exposure period at the exposure point.

As previously stated, the exposure point concentration should be compatible with the toxicity values that will be used to characterize health risks. Chronic and subchronic reference doses are generally based on time-weighted averages of exposure concentrations used in toxicological experiments, and are expressed in terms of an allowable average daily dose. Therefore, the exposure point concentrations used with those reference doses should approximate the time weighted average concentration to which the receptor may be exposed at the exposure point during the exposure period being evaluated. Cancer slope factors are also based on an average daily dose, and exposure point concentrations for evaluating cancer risks should represent the average daily dose for a 30 year exposure.

Four types of exposures are routinely evaluated in disposal site risk assessments: (1) acute (typically 24 hour exposures), (2) subchronic (several months to seven years) exposures to substances with non-carcinogenic effects, (3) chronic exposures (greater than seven years) to substances with non-carcinogenic effects and (4) lifetime exposures (typically 30 years and averaged over a lifetime of 75 years) to carcinogens. For each type of exposure, the risk assessment should focus on the time-segment during which the highest dose is likely to be received. The exposure point concentration should be a conservative estimate of the average exposure concentration over that period of time. For example, to evaluate three month subchronic drinking water exposure when the concentration in the water supply is known to fluctuate seasonally, the exposure point concentration should represent the highest average to which a person could be exposed within a three month time frame.

## **Acute Exposures**

For acute exposure assessments, the exposure point concentration should represent a conservative estimate of the concentration to which a receptor might be exposed over the period of one day. Generally, the highest detected concentration should be employed when one-time exposure could result in adverse health effects.

## **Using Qualified Data**

### **Non-Detects**

In estimating exposure point concentrations, it is not uncommon for the risk assessor to be presented with analytic data for a chemical at the site which includes a number of samples reported to be below the Method Detection Limit (MDL). Such results are referred to as "Non-Detects".

Non-Detect results may be classified into two general situations. First, if a chemical is truly not present at the disposal site (virtually all the samples are reported as Non-Detect), and there is no history of a release of that chemical, then the risk assessor may conclude that the chemical should be dropped from the quantitative risk assessment. Second, if the chemical is reported at the site at concentrations ranging from Non-Detect to some site maximum, the risk assessor may conclude that the reported Non-Detects actually represent a distribution of concentrations between zero and the MDL. These Non-Detect results contribute to the information known about the disposal site and should be incorporated into the quantitative risk assessment in a meaningful way. (There is a third possible situation, where the spatial pattern of positive and Non-Detect results indicate that contamination is localized to specific areas. This would represent a combination of the previous two examples.)

There are several options for the treatment of "Non-Detects" described in the literature (Travis, 1990; Helsel, 1990; Klassen, 1986 and Slymen et al., 1994). The methodologies described include the use of log-probit analysis, maximum likelihood estimation and probability plotting procedures. The level of effort and number of data points required to effectively employ these methods vary, and the risk assessor is encouraged to exercise professional judgement in the selection of a method to treat Non-Detect results.

For estimating exposure point concentrations at most c.21E sites, the Department believes that a more straightforward approach is often appropriate. When a contaminant is detected or likely to be present in the area under investigation and the laboratory reports the concentration of an OHM in a sample taken from the area as "Non-Detect", the concentration of the OHM in that sample should be assumed to

be one-half of the Sample Quantitation Limit (SQL). The SQL is the actual quantitation limit for each analysis, and it accounts for sample dilution that may occur. If only the Method Detection Limit is reported, and if the sample is heavily contaminated with any constituent, the risk assessor should attempt to determine whether the sample was diluted. For samples that have been diluted (a factor of 10 is not unusual), the risk assessor could substantially underestimate the concentration by using the Method Detection Limit or the Practical Quantitation Limit as a basis for the estimate.

This methodology is simple and easy to use. These benefits must be weighed against the bias which is introduced in the resulting EPC estimate. The Non-Detect method selection should also consider, the often high level of uncertainty which is often inherent in environmental sampling and analysis procedures. This uncertainty may result from failure to take an adequate number of samples, mistakes on the part of the sampler, the heterogeneity of the matrix being sampled, and intentional bias in the sample collection. For relatively small disposal sites, these inherent uncertainties may overwhelm the bias introduced by using 1/2 the MDL. A more statistically oriented ND method may not, in such cases, significantly reduce the uncertainty inherent in the resulting EPC. It is up to the risk assessor to judge the level of sophistication appropriate to the data set.

As always, there may be exceptions to this guidance, particularly when the site history and the NDs may indicate the absence of an OHM at a site (or areas within a site). In the latter case, the chemical may be dropped from the quantitative risk assessment or the NDs may be factored into the Exposure Point Concentration as a zero value with appropriate justification.

### **Tentatively Identified Compounds**

Tentatively identified compounds (TICs) are compounds which are detected during sample analysis, but are not target compounds. TICs are often reported when gas-chromatography-mass spectrometry (GC-MS) is used to analyze organic compounds. Target compounds are those for which the instrument was calibrated, using a chemical standard, prior to analysis. The ability of the MS system to store mass spectra electronically in a "library" enables the analyst to compare the library spectra with the spectra produced by a non-target contaminant when one shows up in an environmental sample. Identification based on a "library" comparison is much more uncertain, however, than one based on calibration with a standard for the target compound.

There is no rule of thumb for whether TICs should be included in the risk assessment. Confidence in a TIC identification depends on a number of factors,

including site history and the presence of similar compounds at the site. The EPA's *Guidance for Data Useability in Risk Assessment* provides the following guidance:

Confidence in the identification of a TIC can be increased in several ways. ...An analytical chemist trained in the interpretation of mass spectra and chromatograms can review TIC data and eliminate many false positive identifications. The use of retention indices or relative retention times can confirm TICs identified by the GC-MS computer (Eckel, et al. 1989). Examination of historical data, industry-specific compound lists, compound identifications from iterative sampling episodes, and analyses performed by different laboratories may also increase confidence in the identification of a TIC. The final identification step is to re-analyze the sample after calibrating the GC-MS instrument with an authentic standard of the compound that the TIC is believed to be.

Many compounds that appear as TICs during broad spectrum analyses belong to compound classes. Examples of compound classes are saturated aliphatic hydrocarbons and polycyclic aromatic hydrocarbons (PAHs). The risk assessor may be able to make a preliminary judgement of toxicity at the compound class level without a definitive identification of each compound present.

The identification of a TIC can be confirmed definitively only by further analysis. However, depending on the analytical and historical information available, and the potential impact of the TIC on the results of the risk assessment, confirmatory analysis may not be warranted. The risk assessor should work with the project manager and an analytical chemist to make a prudent decision about the need for follow-up analysis.

### **Measured vs. Modeled Concentrations**

Direct measurement of environmental concentrations is generally preferred, but estimation by an analytical or numerical model may be acceptable when direct measurement is impossible or extremely impractical. If a model is used, modeling methods, input parameters and assumptions, and model validation should be fully referenced and described. Modeling considerations are discussed further in subsequent sections on exposures to specific environmental media.

#### **7.3.3.6 Soil Exposure Point Concentrations**

##### **Direct Contact**

Direct contact with soil can result from such diverse activities as work, play and gardening on residential properties; recreational activities on public and private land; landscaping of commercial properties; grading or excavation of soil for construction or utility repair; agricultural work; outdoor work on industrial properties; and exploration

of any area sufficiently unattractive to appeal to young people's curiosity. Exposure occurs primarily by dermal absorption of contaminants from soil and incidental ingestion of contaminated soil. To calculate an exposure point concentration for a particular exposure scenario, the selected samples should be representative of the area and depth within which the particular exposure is likely to occur.

Generally, for surface soil exposures, **the arithmetic mean soil concentration in an exposure area may be used as the exposure point concentration estimate.** The accuracy of this method depends on three underlying assumptions:

- Over time, soil concentrations remain constant;
- The detected concentrations represent a uniform or random distribution of soil samples over the exposure area; and
- Over time, exposure is equally likely at any location within the exposure area.

If these assumptions hold true, the arithmetic mean concentration in the exposure area will represent the arithmetic mean concentrations with which a person comes into contact over time. In other words, the spatial average may be used as a surrogate for the temporal average.

The first assumption stated above is consistent with current DEP practices. Laboratory derived degradation rates often are not observed in the field, and the conservative assumption that concentrations will not decrease over the time of the exposure period is encouraged.

There are cases, however, when the second and/or third assumptions do not hold true. Sampling locations are not always distributed evenly over the site, and exposure frequencies are often higher in some areas than others. In these cases, a weighted average of the detected concentrations should be used.

Figure 7.7 illustrates a situation where the sampling points are not evenly distributed over the site. In this example, an area weighted average exposure point concentration is considered to be a representative estimate of the exposures at the site over time. In this method, analytical data should be weighted in a manner which reflects the sampling frequency as follows:

*If 6 equidistant samples were taken in a portion of a site approximately 10 meters by 60 meters each sample can be said to represent  $100 \text{ m}^2$  ( $600 \text{ m}^2/6 \text{ samples}$ ). If two additional equidistant samples were obtained from another portion of the site approximately 10 meters by 40 meters, each sample could be said to represent  $200 \text{ m}^2$ . The sample values should be weighted according to the relative area each represents. The area-weighted average obtained from this exercise represents the arithmetic mean concentration over the exposure area. If*

*exposures are equally likely throughout the entire area over time, this area-weighted average also represents the time-weighted average, or the average exposure concentration over time.*

Figure 7.8 illustrates a scenario where the sampling locations are distributed evenly, but exposure occurs more frequently in one portion of the site than the other. In this example, a person is not equally likely to be exposed at all locations, and the time-weighted average could account for different exposure frequencies in different areas as follows:

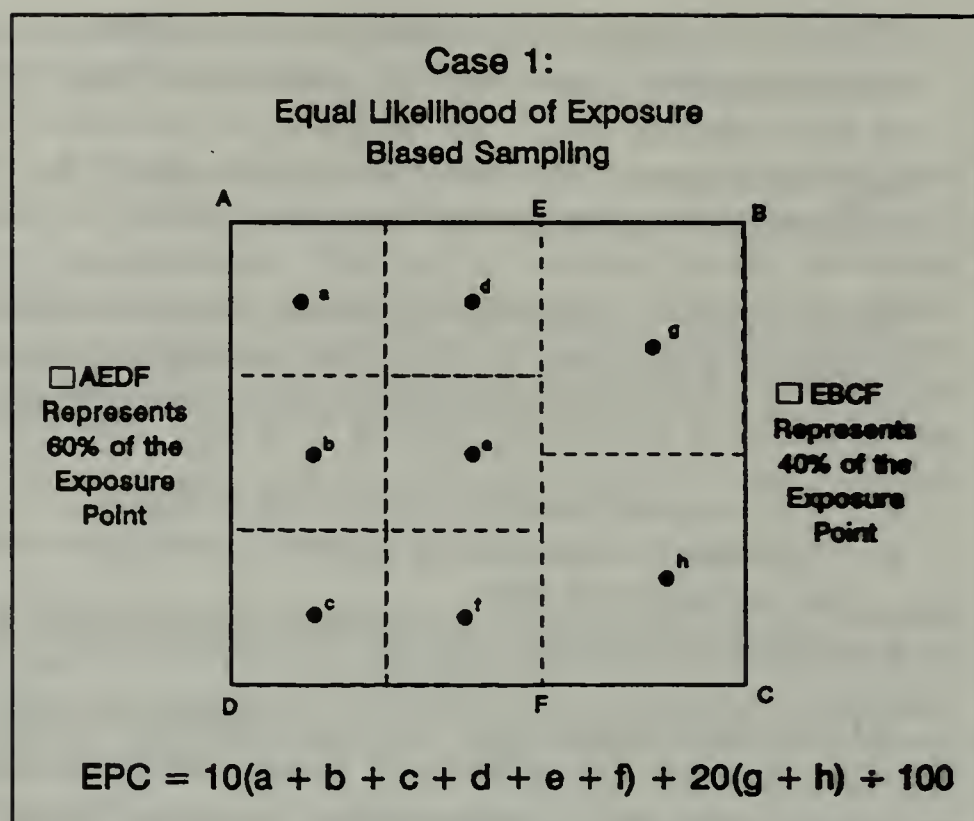


Figure 7.7

*If 90% of the exposure time takes place on half of the site, and 10% of the exposure time takes place on the other half of the site. The average concentration for each half could be calculated separately, and then weighted to obtain a frequency-weighted average. Again the result represents the arithmetic mean of the concentrations to which the person is exposed over time.*

Note that there may be situations in which weighting for both exposure time and area are appropriate.

These examples represent simple approaches to obtaining a weighted average. More refined techniques for weighting soil or sediment data to estimate an areal average are available. Those that appear to be best suited for exposure assessment are polygon techniques. In general, these procedures involve construction of a polygon around each data point so that each polygon contains the locations that are closer to the data point at its center than any other data point. Such methods are useful for deriving area weighted average soil concentrations which may be used as surrogates for time-weighted exposure point concentrations.

Other approaches often suggested in risk assessment literature and guidance are oriented toward estimating the most likely concentrations at locations between data points. Kriging and triangulation are examples of such methods. The problem of determining

concentrations between data points is related to but different from the problem of estimating the average concentration over an exposure area. To date, DEP has found no compelling argument for the applicability and utility of these techniques for calculating exposure point concentrations, and therefore recommends against employing them at this time.

### Composite Soil Samples

The concentration of a composite soil sample may be used to approximate the arithmetic average of the subsample concentrations. The use of composites can provide an arithmetic mean concentration of several locations at the same cost as analyzing an individual sample. However, the concentration detected in a composite is representative of the average concentration of subsamples only if: (1) the subsamples are representative of the exposure area (2) the composite sample is well mixed and (3) the process of compositing does not result in analyte loss. These conditions can be verified by comparing the average concentration of a set of single location samples with the concentration of a composite of sample collected from the same area. If a composite sample from one area is checked in this manner and demonstrated to be accurate for each sampling event, it is not necessary to check all composites from all areas.

### Consumption of Homegrown Fruits and Vegetables

Consumption of fruits and vegetables grown in contaminated soil will result in exposure if the plant takes up a portion of contaminant from the soil. Ideally, produce concentrations should be measured directly. However, sometimes produce concentration data cannot be obtained quickly enough to be used in site management decisions, and must therefore be estimated from soil concentration data. The contaminant concentration in the produce itself is related to the soil concentration and the plant uptake factor, as follows:

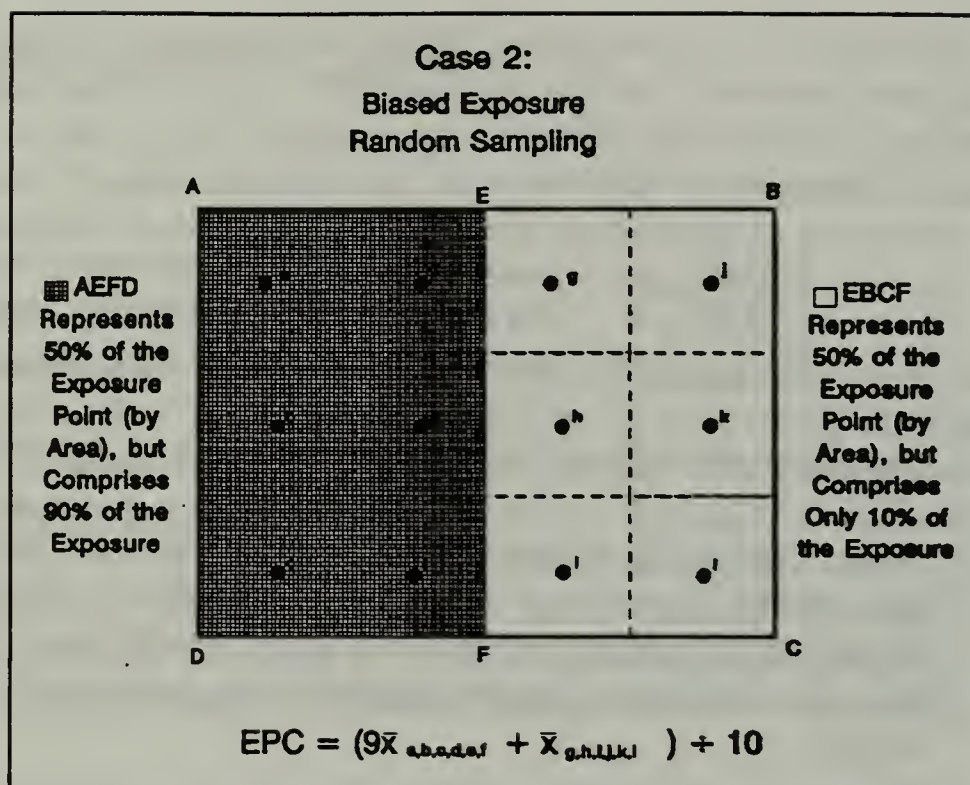


Figure 7.8

$$[OHM]_{plant} = [OHM]_{soil} \times Ksp_{plant/soil} \quad (7-8)$$

Where:

$$\begin{aligned} [OHM]_{plant} &= \text{plant contaminant concentration (mg}_{OHM}/\text{kg}_{plant}) \\ [OHM]_{soil} &= \text{soil contaminant concentration (mg}_{OHM}/\text{kg}_{soil}) \\ Ksp_{plant/soil} &= \text{plant/soil uptake factor (kg}_{soil}/\text{kg}_{plant}) \end{aligned}$$

Default plant/soil uptake factors are listed in Appendix B.

When estimating contaminant concentrations in produce, it is necessary to assure that the uptake factors and produce consumption estimates are compatible. Plant uptake factors are generally reported on a dry weight basis. Dry weight produce concentrations must be used with intake estimates that are expressed in terms of dry weight, not wet weight.

### Inhalation of Particulate Matter from Contaminated Soil

Inhalation of contaminated particulate matter is of concern in cases where contaminated soil is unvegetated or is likely to be graded or excavated for site work or for development.

The exposure point concentration (mass of contaminant/volume air) should be calculated as follows:

$$EPC_{air} = [OHM]_{soil} \times PM_{10} \times CF \quad (7-9)$$

Where:

$$\begin{aligned} EPC_{air} &= \text{Exposure Point Concentration (}\mu\text{g}_{contaminant}/\text{m}^3_{air}) \\ [OHM]_{soil} &= \text{Soil concentration (mg}_{contaminant}/\text{kg}_{soil}) \\ PM_{10} &= \text{Respirable particulate concentration in air (}\mu\text{g}/\text{m}^3_{air}) \\ CF &= \text{Conversion factor (10}^{-9} \text{ kg}/\mu\text{g}) \end{aligned}$$

When evaluating exposure to airborne particulate matter at a sparsely vegetated or unvegetated site, or at a construction site, it should be assumed that all of the PM10 is contributed by the contaminated area. This may overestimate the contribution of site soil to airborne particulate concentrations, but the data necessary to obtain a more accurate estimate for these conditions is not available. On a site-specific basis, with appropriate justification (e.g. dense vegetation), the percentage of PM10 that is soil-derived may be reduced to as low as 40% (Thurston and Spengler, 1983).

It may generally be assumed that the concentration of the contaminant in PM10 is equal to the concentration of the contaminant in soil. This assumption may underestimate the concentration of contaminant in the PM10 fraction, since smaller particulate fractions sometimes contain contaminant concentrations that are enriched relative to larger fractions. However, the data needed to derive more accurate concentration estimates is not available.

Ideally, to assess current conditions, both the concentration of PM10 in the air and the concentrations of contaminants in the PM10 fraction should be measured directly. However, to assess future conditions, it is necessary to estimate the contaminant concentrations in air from the contaminant concentrations in soil. Default values for air concentrations of PM10 from one of two situations are usually required. The first situation is an open field condition, in which contaminated soil is sparsely vegetated or bare, and soil particulate matter readily becomes airborne. The second is a grading or excavation scenario, in which earth working activities may raise elevated levels of dust.

For open field situations,  $29 \mu\text{g}/\text{m}^3$  should be used as an estimate of the ambient PM10 concentration. This value represents the maximum annual arithmetic mean concentration measured in Massachusetts in 1994 by DEP's Air Quality Surveillance Branch (1994 Air Quality Report, Commonwealth of Massachusetts). A contribution factor of 100% should be used to estimate the contribution of soil to airborne particulate matter/TSP concentrations under sparsely vegetated open field conditions. If particulate exposures are being evaluated for heavily vegetated open field conditions, the contribution factor may range from 100% to 40%.

For grading and excavation scenarios, a PM10 value of 50 should be used to estimate ambient concentrations. This value (rounded from 49.6) is the arithmetic mean of the 24 hour maximum PM10 values from 20 sampling locations in the Commonwealth during 1994 (1994 Air Quality Report, Commonwealth of Massachusetts). A contribution factor of 100% should be used to estimate the portion of ambient particulate level contributed by the construction activities.

There are a number of uncertainties associated with use of the default PM10 values, including:

- The published 24 hour averages may underestimate PM10 concentrations attained during the work day.
- The sampling locations are not necessarily located near construction activities or large areas of sparsely vegetated soil.

Therefore, these PM10 values are recommended for use only in the absence of more representative data.

### **7.3.3.7 Groundwater Exposure Point Concentrations**

#### **Private Wells**

##### **Exposure Points**

Within a GW-1 area, the risk assessment should address both the risks associated with any well in use and the foreseeable risks from the installation of a private supply well anywhere within the contaminated area. Thus, the exposure points of concern should include both existing wells and the groundwater at any location where a well could potentially be installed. In other words, the groundwater at each monitoring well should be considered a foreseeable exposure point.

Thus, regardless of the risk assessment method employed, **exposure point concentrations and risks should be evaluated separately for each well in use and for each location (monitoring well) where a well could be installed within the contaminated area.** The risk assessor should assume that any one individual would be exposed only to water from one supply well. A single exposure point concentration should include data from locations within an area likely to be influenced by one supply well.

In general, BWSC recommends against averaging concentrations detected in different monitoring wells because monitoring wells are seldom clustered closely enough to lie within an area that would affect a single well. However, in exceptional cases where the locations of monitoring wells are clustered closely enough so that several would sample from an area of groundwater from which a single private supply well could draw, concentrations may be averaged.

The monitoring wells with the highest levels of contamination should be selected to represent potential supply well locations for the risk assessment. At some sites, one monitoring well may clearly represent the highest contaminant levels. At other sites where the groundwater is contaminated by a mixture of substances of varying relative concentrations, several monitoring wells may have to be evaluated as potential supply well locations.

##### **Averaging Periods**

The exposure point concentration for a private well should represent an estimate of the average concentration to which a user is likely to be exposed over the period of

concern. Lifetime exposure assessments are based on a 30 year time period, chronic exposure evaluations typically focus on a seven year period, and subchronic exposure evaluations focus on period of three months (sometimes longer, but always less than seven years). Thus, the exposure point concentration should represent an estimate of a one year, seven year or lifetime average.

A three month average for a subchronic evaluation should be based on samples collected at a time when the concentrations can reasonably be expected to represent a maximum for the year. One sampling round is generally insufficient to obtain a reliable concentration estimate, and, confirmatory samples should always be collected.

Of course, site management decisions have to be made within time periods that are much shorter than seven years or a lifetime. Unless, as is discussed in the following paragraph, there is evidence that contaminant levels are increasing, it is reasonable to use the current annual average as an estimate of the seven year or lifetime average.

If the data suggest or show an increasing trend, the exposure point concentration estimate should reflect the predicted increase, and the assessment report should fully describe uncertainty about that estimate. However, such an estimate should only be used for preliminary site management decisions. Given the uncertainty associated with exposure estimates for wells where contamination is increasing, such estimates should not be used to support a conclusion that "no further action" is required.

If the data show a decreasing trend, it may be appropriate to use current values as an estimate of the long-term average. Including historical data in the calculation may lead to exposure estimates that are not consistent with respect to current or future conditions, and could lead to risk management decisions that are problematic. For example, it would be inappropriate to conclude that groundwater remediation is necessary in a situation where the concentrations are already below levels of concern for human health and are continuing to decrease.

### **Use of Mathematical Models**

The use of mathematical models to estimate current exposure point concentrations for private wells is inappropriate. Existing wells should be sampled on a continuing basis to determine representative exposure point concentrations. Samples from the most highly contaminated monitoring wells (in or upgradient from the GW-1 area) should be used to represent potential exposures under foreseeable use and future conditions.

## To Filter or Not to Filter

The nature of the samples analyzed to obtain exposure point concentrations at private water supplies should represent, as closely as possible, the nature of the water drawn from the wells in question. Often the water drawn from a private supply well is unfiltered, so, in theory, unfiltered groundwater samples from monitoring wells should be used to estimate potential exposure point concentrations. However, monitoring wells, especially newly developed monitoring wells, often produce samples that are quite turbid, and obviously are not representative of water that would be drawn from a supply well. For example, if the water from a monitoring well exceeds the turbidity standard for drinking water, it is reasonable to assume that the particulate levels are not representative of the water being drawn from the supply well. In such cases, BWSC recommends using **filtered samples** to estimate exposure point concentrations.

A promising alternative to filtering is using a peristaltic pump to purge monitoring wells and collect groundwater. In comparison to samples collected with a bailer, peristaltic pumps operated at a low flow rate (0.2 liters per minute) have reportedly produced samples that are less turbid and more representative with respect to groundwater metals concentrations (Acquisition of Representative Ground Water Quality Samples for Metals. Robert W. Puls and Robert M. Powell, *Ground Water Monitoring Review*. Summer 1992.) Although this technique has not been universally accepted or widely applied in field investigations to date, it appears to offer a reasonable alternative to the choice between filtering and not filtering, both of which have serious drawbacks. ORS would consider samples collected at low flow from monitoring wells to be reasonably representative of water drawn from a private supply well at the same location.

## EPCs For Comparison to Drinking Water Standards

Massachusetts Drinking Water Quality Standards (310 CMR 22) are compared to exposure point concentrations as applicable suitably analogous standards. Each exposure point concentration, including those measured at monitoring wells, is compared with drinking water standards as a component of the Method 3 risk characterization. The drinking water quality regulations should be consulted for details concerning sampling and analysis required as part of these regulations. In general, the MMCLs are compared with average exposure point concentrations. For public water supply wells, the average of four quarterly samples is used.

## Public Wells

Exposure point concentrations representing current conditions at public water supply wells are measured directly at the wellhead. Samples collected for baseline risk assessment purposes should represent pre-mixing, pre-treatment conditions. Neither mixing nor well head treatment is considered permanent, and these risk reduction activities should not be considered when estimating a baseline exposure point concentration.

Estimating exposure point concentrations under future conditions for public water supply wells is slightly more complicated than for private supplies. At supply wells located some distance away from the contamination source area, future concentrations depend on contaminant fate and transport processes such as dilution and dispersion. Even in future public supply wells that could potentially be installed in the most highly contaminated area, the exposure point concentrations are likely to be lower than current monitoring well concentrations because of dilution during pumping. As a consequence, a predictive model is needed to estimate exposure point concentrations at a public supply well under future conditions. Either a simple analytical model or a complex numerical model may be used.

BWSC generally recommends the use of a simple, conservative analytical approach to predict concentrations under future conditions. The results of a complex numerical model will not affect the conclusion of the risk assessment because of the requirement to characterize foreseeable risks by comparing standards to concentrations at each foreseeable exposure point. **The MCP requires the comparison of all current and foreseeable exposure point concentrations in GW-1 areas to applicable or suitably analogous standards (310 CMR 40.0993(3)).** Thus, current groundwater concentrations at each monitoring well in a GW-1 area must be compared with drinking water standards. If the monitoring well concentration exceeds the standard, the risk assessment will conclude that Significant Risk of harm to public health exists. This direct comparison of groundwater concentrations to standards is more likely to indicate the need for remediation than are risk estimates based on a model that incorporates dilution. Since modeled concentrations are not likely to affect the conclusions of the risk assessment, extensive mathematical modeling efforts are seldom warranted.

### **7.3.3.8 Indoor Air Exposure Point Concentrations**

At disposal sites where soil or groundwater beneath a building is contaminated with volatile organic compounds, the potential for exposure to those substances must be considered in the human health risk assessment. Organic compounds can accumulate in indoor air by migrating from soil or groundwater, through the soil gas in the overlying unsaturated soil and into buildings through pores, cracks or openings in the foundation.

Exposure point concentrations in the air in any particular building are dependent upon a combination of conditions:

- The Henry's Law coefficients of the contaminant of concern, which provides an indication of their tendency to partition from the groundwater to the air spaces in the overlying soil
- the concentrations of contaminant in the groundwater
- the depth of the water table below the surface of the soil
- the depth of the groundwater table below the building structure
- the physical characteristics of the soil at the location of concern
- the structure of the building
- the heating and ventilation features of the building which affect the rate at which soil gas will enter the building.

### Measurement vs Modeling

The two basic approaches to estimating indoor air concentrations are direct measurement (air sampling followed by laboratory analysis) and estimation using a contaminant transport model. While each approach has advantages and disadvantages, direct measurement is preferable overall and is generally recommended for evaluating conditions in existing buildings associated with current groundwater concentrations.

It is often difficult to model indoor air concentrations with confidence from concentrations detected in groundwater, or even soil gas, for three reasons. First, the information needed to determine the validity of a model for a particular location and building is often not available. Second, the site-specific soil and building parameters needed to accurately model transport at a specific site may not be available. Third, models generally focus on water-soil gas partitioning and soil gas-indoor air diffusion, and don't account for other transport pathways, such as utility lines, that may provide the dominant migration route into a particular building.

Direct measurement also has some drawbacks. It is more resource intensive than modeling, and it is often logistically challenging. One of the most serious technical concerns is the fact that a single measurement event cannot provide an integrated estimate of the exposure point concentration over time. Indoor air concentrations in a building are heavily influenced by weather and by variations in use and activities. Thus, indoor air concentrations can vary substantially over time, and it may not be possible to predict whether concentrations at a given point in time represent a high, low or average estimate. (It should be noted that modeling does not necessarily provide an integrated estimate either, but the problem of temporal variation can be addressed to some extent by the selection of conservative modeling parameters; after that the question is generally set aside.)

The following sections discuss measurement and modeling considerations in more detail.

### **Indoor Air Sampling**

To obtain a representative estimate of the concentration to which a person is likely to be exposed over time in a building, sampling locations, times, and methodology must be planned carefully. Each of these considerations is discussed briefly in the following paragraphs.

#### **Sampling Locations**

Sampling locations should include areas where concentrations are likely to be highest and areas where the frequency and duration of exposure is high. Concentrations are normally expected to be highest in the basement, if there is one. However, people who live or work in the building are likely to spend more time in other areas. Results from all areas of a building should be incorporated in the exposure point concentration estimates, but data from different areas should be weighted to reflect exposure frequency. Samples from various rooms in a living area or a commercial building can vary substantially, so a number of areas should be sampled during each sampling round.

#### **Sampling Over Time**

In planning a sampling program, both **sampling time** and **sampling duration** are important to consider in obtaining a representative estimate.

In most buildings where volatile organic compounds migrate from groundwater into indoor air, the indoor air concentrations are likely to vary substantially over time. Seasonal changes in the depth to groundwater, temperature, and in building use can affect indoor air concentrations. Even daily changes in ambient air pressure may have a significant effect. For a long-term exposure evaluation (as opposed to an imminent hazard evaluation) sampling should be conducted several times a year. However, air sampling is time consuming and expensive, and it is not always possible to obtain samples that fully reflect temporal variations in concentration.

If sampling is only to be done once or twice because of resource constraints, the site assessment report must demonstrate that the concentrations would be highest at those times, considering depth to groundwater, heating system operating conditions, and building tightness (closed doors and windows).

The sampling duration should correspond as closely as possible to the duration of the exposure being evaluated. Since the duration of most indoor air sampling events ranges from a couple of hours to a day, and the results are often used to evaluate subchronic exposures (longer than a few months) and chronic exposures (longer than seven years), sampling durations should be as long as possible. Other factors that affect sampling duration are discussed in the following section on Sampling and Analysis Methodology.

### **Sampling and Analysis Methodology**

Although an extensive discussion of sampling and analysis methodology is beyond the scope of this guidance, a few words of caution may be appropriate. Air sampling should be planned and conducted by specialists in the field. Designing and executing an air sampling program requires a thorough understanding of the complexities and subtleties of air sampling theory and technology.

Method validation is crucial in enabling risk managers to make reasonable decisions based on sampling results. When available and appropriate, standard EPA methods should be employed. However, the utility of a standard method to the specific situation of concern should always be carefully evaluated.

Method sensitivity is one factor that often limits the applicability of standard methods at specific exposure situations. Because air intake rates are high relative to drinking water intake or soil intake rates, the concentration of a substance in air that is associated with a significant risk is relatively low. Therefore, it is particularly important to verify that a proposed air sampling methodology can achieve the necessary detection limits before conducting a sampling program.

Whatever the duration of an indoor air sampling event (from several hours to one day), the results are usually used to represent exposures that occur over much longer periods of time (from several months to a lifetime). In planning the duration of a sampling event, a balance must be struck between the need to collect samples that are reasonably representative of long term exposures and the technical constraints of available technologies. In many cases, the sampling duration is limited by the potential for breakthrough (desorption of contamination from the sample collection medium), which can be a serious problem if the volume of air drawn through the sampling tube is higher than that specified in the protocols. In some cases, a lower flow rate can be used to achieve a longer sampling duration. Again, it is recommended that sampling plans be developed by specialists with extensive experience in order plan flow rates and sampling durations that balance risk assessment and technical considerations.

## **Modeling Indoor Air Concentrations**

Before a model is used, the validity of the model for conditions similar to those at the location of concern must be determined. **Precedent is not an indication of validation.** Validation must include obtaining or identifying data showing that the model can predict indoor air concentrations with a degree of accuracy that is sufficient for the risk assessment and the risk management decisions at hand.

Both groundwater and soil gas concentrations have been used as source terms for models. In principle, soil gas concentrations offer a preferable starting point, since they eliminate the need to model partitioning from groundwater into soil gas, and thus eliminate a significant source of uncertainty about the final estimate. However, soil gas measurements have a somewhat uneven track record, and in many cases, potential error associated with measuring soil gas concentrations may be a larger source of uncertainty than the partition model.

(MADEP/ORS is in the process of determining whether there are any existing models that are generally valid and conservative and could be considered default models).

### **7.3.3.9 Exposure Point Concentrations Related To Surface Water and Sediment Contamination**

#### **Fish Consumption**

Exposure point concentrations for fish consumption should be consistent with the type of exposure being evaluated. For chronic and subchronic exposure point concentration estimates, an average of the concentration detected in tissue of individual fish fillets may be used to represent the average concentration in fish that a person might consume over time. Ideally, sufficient data would be available to calculate exposure point concentrations for each fish species present so that the risk assessment could consider exposures to populations partial to eating certain species. For substances that could have acute toxic effects, the highest concentration detected should be used as the exposure point concentration estimate when evaluating the risks from acute exposures.

In many cases, it is not possible to obtain a large enough number of fish to calculate an average concentration with a reasonable degree of certainty. The risk assessor and project manager must then decide how to deal with the uncertainty. One option would be to use an upper Confidence Limit on the mean as a conservative estimate of the average concentration. An alternative would be to describe the uncertainty in the assessment report, and compensate for it by making a very conservative risk

management decision. However, a sample number smaller than three would be insufficient basis for a public health-protective decision.

Appendix D contains a detailed discussion of fish tissue sampling and analysis considerations.

### **Swimming**

Sediment and surface water exposure point concentrations used to evaluate swimming and wading exposures should represent conservative estimates of the arithmetic mean concentration in the shoreline area used for swimming or wading. If contamination is reaching a surface water body by groundwater discharge or by surface runoff, near shore areas may be more heavily contaminated. Concentrations of samples collected over large areas of a water body will not necessarily be representative, and should not be averaged. Likewise, if a model is used to predict concentrations likely to be attained in the future, the model should focus on the near shore area, and not the entire water body.

## **7.3.4 Exposure Equations**

The following equations, organized by exposure medium, are provided to assist the risk assessor in quantifying a receptor's potential exposure to oil or hazardous material at a c.21E disposal site. The variables specific to each equation are discussed in this section while variables common to most of the equations were presented in the previous section. Default assumptions for these variables are provided in Appendix B.

### **7.3.4.1 Air**

The toxicity information generally used to evaluate the risk of harm to health associated with inhalation exposures, Reference Concentrations and Units Risk values, are air *concentrations*. These values are intended to be used in combination with Average Daily Exposures expressed as applied concentrations, *not* dose. In the absence of RfCs or Unit Risk values, an oral Reference Dose or Slope Factor may be used to estimate risk either by: (a) calculating an Average Daily Dose from the inhalation pathway; or (b) converting the Reference Dose to a Reference Concentration and the Slope Factor to a Unit Risk. Thus, the equation chosen to evaluate the site inhalation exposures will depend upon the availability and nature of the toxicity information.

### **Calculation of Average Daily Exposure<sub>air</sub>**

Gaseous oil or hazardous material (for example, OHM volatilized from contaminated soil or groundwater) may be inhaled by the receptor of concern whenever the receptor

is near the disposal site. The Average Daily Exposure to the contaminated air ( $ADE_{air}$ ) is dependent upon the frequency and duration of the assumed exposures. The result of this calculation should be an estimate of applied concentration, not dose. Note that the equation is a simple adjustment of the exposure point concentration to account for the amount of time the receptor spends in the area with contaminated air.

$$ADE_{air} = \frac{[OHM]_{air} * EF * ED * EP * C}{AP} \quad (7-10)$$

Where:

- $[OHM]_{air}$  = Exposure point concentration of gaseous oil or hazardous material in the air at the Exposure Point during the period of exposure (dimensions: mass/volume; typical units:  $\mu g/m^3$ ).
- EF = Number of exposure events (frequency) during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)
- ED = Duration of each exposure event (dimensions: time/event; typical units: hours/event)
- EP = Duration of the exposure period (dimensions: time; typical units: years)
- AP = Averaging Period (dimension: time; typical units: years)
- C = Appropriate units conversion factor(s) (e.g.,  $10^{-6}$  kg/mg, 1 week/7 days)

For receptors assumed to be exposed constantly (such as for many residential exposures), the Average Daily Exposure would be equal to the Exposure Point Concentration:

$$ADE_{air} = \frac{[OHM]_{air} * 1 \frac{event}{day} * 24 \frac{hours}{event} * 6 years * \frac{1 day}{24 hours}}{6 years} \quad (7-11)$$

$$ADE_{air} = [OHM]_{air} \quad (7-12)$$

### Calculation of Average Daily Dose<sub>air</sub>

As noted above, there are circumstances under which the dose or hazardous material experienced by a receptor breathing contaminated air may be calculated. The equation for estimating such an Average Daily Dose ( $ADD_{air}$ ) is given as:

$$ADD_{\text{gaseous OHM}} = \frac{[OHM]_{\text{air}} * VR * RAF * EF * ED * EP * C}{BW * AP} \quad (7-13)$$

Where:

- [OHM]<sub>air</sub> = Exposure point concentration of gaseous oil or hazardous material in the air at the Exposure Point during the period of exposure (dimensions: mass/volume; typical units:  $\mu\text{g}/\text{m}^3$ )
- VR = Ventilation (inhalation) rate for the receptor of concern during the period of exposure. (dimensions: volume/time; typical units:  $\text{m}^3/\text{hour}$ )
- RAF = Relative Absorption Factor (unitless)
- EF = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)
- ED = Duration of each exposure event (dimensions: time/event; typical units: hours/event)
- EP = Duration of the exposure period (dimensions: time; typical units: years)
- BW = Body weight of the receptor of concern during the averaging period (dimension: mass; typical units: kg)
- AP = Averaging Period (dimension: time; typical units: years)
- C = Appropriate units conversion factor(s) (e.g.,  $10^{-6}$  kg/mg, 1 week/7 days)

#### 7.3.4.2 Soil

The Average Daily Dose received by a receptor via direct contact with soil containing OHM ( $ADD_{\text{soil}}$ ) is the sum of the average daily doses resulting from absorption via dermal contact with the contaminated soil and the incidental ingestion of that soil.

$$ADD_{\text{Soil}} = ADD_{\text{dermal absorption}} + ADD_{\text{ingestion}} [ + ADD_{\text{particulate inhalation}} ] \quad (7-14)$$

Additional soil-related exposures may result from the inhalation of fugitive dust originating from the contaminated soil.

*Note: The general procedures for assessing soil exposure described in this section have been adapted from an on-going project within the Office of Research and Standards to develop methodology for deriving soil advisory levels (MADEP, 1995b).*

#### Dermal Contact with Contaminated Soil

Dermal absorption of oil or hazardous material is a potentially significant route of exposure whenever direct contact with soil may occur. In fact, dermal absorption from soils may be more significant than incidental ingestion for chemicals which have a percent absorption exceeding about 10% (USEPA, 1992). (Even chemicals exhibiting percentage absorption less than 10% may contribute significantly to cumulative risk estimates and thus, these chemicals must also be evaluated.) The absorption of OHM

from soil depends upon chemical-specific factors as well as the characteristics of the soil (such as particle size and organic carbon content).

The Average Daily Dose due to dermal contact with OHM contaminated soil ( $ADD_{\text{dermal absorption}}$ ) may be calculated:

$$ADD_{\text{dermal absorption}} = \frac{[OHM]_{\text{soil}} * SA * AF * RAF * EF * ED * EP * C}{BW * AP} \quad (7-15)$$

Where:

- $[OHM]_{\text{soil}}$  = Representative concentration of OHM in the soil at the exposure point during the period of exposure (dimensions: mass/mass)
- SA = Skin surface area in contact with the soil on days exposed (dimensions: area/time)
- AF = Mass of soil adhered to the unit surface area of skin exposed (dimensions: mass/area)
- RAF = Relative Absorption Factor (unitless)
- EF = Exposure Frequency: the number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
- ED = Exposure Duration: the typical duration of each exposure event (dimensions: time/event)
- EP = Exposure Period: the period of time over which exposure may occur (dimension: time)
- BW = Body Weight of the receptor of concern during the averaging period (dimension: mass)
- AP = Averaging Period (dimension: time)
- C = Appropriate units conversion factor(s)

### Incidental Ingestion of Contaminated Soil

The Average Daily Dose due to the incidental ingestion of OHM contaminated soil ( $ADD_{\text{soil}}$ ) may be calculated:

$$ADD_{\text{ingestion}} = \frac{[OHM]_{\text{soil}} * IR * RAF * EF * ED * EP * C}{BW * AP} \quad (7-16)$$

Where:

- $ADD_{\text{ing}}$  = Average daily dose of oil or hazardous material received through the ingestion of soil, during the period of exposure (dimensions: mass/mass-time, typical units: mg/kg-day).
- $[OHM]_{\text{soil}}$  = Exposure point concentration of the oil or hazardous material in soil (dimensions: mass/mass, typical units: mg/kg).
- IR = Daily soil ingestion rate on days exposed during the exposure period (dimensions: mass/time, typical units: mg/day)
- RAF = Relative Absorption Factor (dimensionless).
- EF = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time, typical units: events/day).
- ED = Average duration of each exposure event (dimensions: time/event, typical units: day/event).
- EP = Duration of the exposure period (dimensions: time, typical units: years).
- C = Appropriate units conversion factor(s)

BW = Body weight of the receptor of concern during the averaging period (dimensions: mass, typical units: kg).  
 AP = Averaging Period (dimension: time, typical units: years).

### DERMAL EXPOSURES: COMPARISON WITH EPA-RECOMMENDED METHOD

Equation 7-15 incorporates the USEPA recommended approach of estimating dermally absorbed doses from any chemical present in soil. The USEPA equation (USEPA, 1992; equation 6.18) is based upon an experimentally determined (or theoretically derived) absorption fraction (ABS) to determine the absorbed dose per event:

$$DA_{\text{event}} = C_{\text{soil}} * AF * ABS \quad (7-17)$$

Where:

DA<sub>event</sub> = Absorbed dose per event (mg/cm<sup>2</sup>-event)  
 C<sub>soil</sub> = Contaminant concentration in soil (mg/kg)(10<sup>-6</sup> kg/mg)  
 AF = Adherence factor of soil to skin (mg/cm<sup>2</sup>-event)  
 ABS = Absorption Fraction

Note that C<sub>soil</sub> and AF of the USEPA equation correspond to [OHM]<sub>soil</sub> and AF in Equation 7-15. The Absorption Fraction (ABS) of the USEPA equation is incorporated into the Relative Absorption Factor (RAF) shown in Equation 7-15 (See Section 7.2.3 for a discussion of the derivation of RAFs).

This comparison of USEPA and MADEP approaches is included here to address a common misperception that EPA guidance recommends evaluating dermal absorption for only cadmium and PCBs.

### Inhalation of OHM Contaminated Particulates

Airborne particulates (fugitive dust) may carry oil or hazardous material to receptors, resulting in soil-related inhalation exposures. An Average Daily Dose due to the inhalation of OHM contaminated particulates (ADD<sub>inhp</sub>) may be calculated:

$$ADD_{\text{particulate inhalation}} = \frac{[RP]_{\text{air}} * [OHM]_{\text{particulate}} * VR * RAF * EF * ED * EP * C}{BW * AP} \quad (7-18)$$

Where:

$[RP]_{air}$	=	Exposure point concentration of respirable particulates (i.e., $PM_{10}$ ) in the air at the Exposure Point during the exposure event. (dimensions: mass/volume; typical units: $\mu g/m^3$ )
$[OHM]_{part}$	=	Representative concentration of OHM in the respirable particulates at the Exposure Point during the period of exposure. (dimensions: mass/mass; typical units: mg/kg)
VR	=	Ventilation (inhalation) rate for the receptor of concern during the period of exposure. (dimensions: volume/time; typical units: $m^3$ /hour)
RAF	=	Relative Absorption Factor (dimensionless)
EF	=	Number of exposure events during the exposure period divided by the number of days in the exposure period. (dimensions: events/time; typical units: events/day)
ED	=	Duration of each exposure event. (dimensions: time/event; typical units: hours/event)
EP	=	Duration of the exposure period (dimensions: time; typical units: years)
BW	=	Body weight of the receptor of concern during the averaging period (dimension: mass; typical units: kg)
AP	=	Averaging Period (dimension: time; typical units: years)
C	=	Appropriate units conversion factor(s)

For airborne chemicals which act at the point of contact (e.g. the lungs) when inhaled, the Average Daily Exposure of these chemicals calculated in the manner described in Section 7.3.4.1 would be used in combination with a *Reference Concentration* or *Unit Risk* to estimate potential risks. Under such conditions, the  $ADD_{particulate\ inhalation}$  would not be calculated.

In situations with high particulate concentrations, the larger (greater than  $10\ \mu m$ ) inhaled particulates may result in significant oral exposures which should also be quantified.

#### 7.3.4.3 Sediment

The Average Daily Dose received by a receptor via direct contact (dermal absorption and incidental ingestion) with OHM contaminated sediment will be estimated in a manner similar to the calculation of the ADD for soil exposure, including both dermal contact with the sediment and incidental ingestion of that sediment. The inhalation of fugitive dust originating from contaminated sediments would not generally be evaluated unless climatic conditions resulted in such sediments becoming dry, thus increasing the potential for dust generation.

#### 7.3.4.4 Drinking Water

The exposure experienced by a receptor using contaminated water is not limited to exposure received when actually drinking the water. Several studies indicate that significant exposure may also result from the inhalation of material volatilized from the water and through the absorption of contaminants from water in contact with the receptor's skin (Jo et al., 1990a and 1990b). Each of these exposure pathways should be

evaluated separately, as described herein. The calculated oral and dermal doses are assumed to be equitoxic and may be mathematically combined:

$$ADD_{\text{oral, dermal}} = ADD_{\text{oral}} + ADD_{\text{dermal}} \quad (7-19)$$

The assumption of equitoxicity is not assumed to apply to the dose received via the inhalation of volatilized material from the water, and the risk associated with this exposure must be evaluated separately using appropriate toxicity information.

### Ingestion of Contaminated Drinking Water

The Average Daily Dose due to the ingestion of OHM contaminated drinking water ( $ADD_{\text{dwi}}$ ) may be calculated:

$$ADD_{\text{ingestion}} = \frac{[OHM]_{\text{water}} * VI * RAF * EF * ED * EP * C}{BW * AP} \quad (7-20)$$

Where:

$[OHM]_{\text{water}}$ =	Exposure point concentration of oil or hazardous material in the drinking water at the exposure point during the exposure period (dimensions: mass/volume; typical units: $\mu\text{g/liter}$ )
VI =	Volume of drinking water ingested by the receptor of concern at (or from) the exposure point during the exposure period (dimensions: volume/time; typical units: liters/day)
RAF =	Relative Absorption Factor (unitless)
EF =	The exposure frequency, or the number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day)
ED =	Duration of each exposure event (dimensions: time/event; typical units = days/event)
EP =	Duration of the exposure period (dimension: time; typical units: years)
BW =	Body weight of the receptor of concern during the averaging period (dimensions: mass; typical units: kg)
AP =	Averaging Period (dimension: time)
C =	Appropriate units conversion factor(s)

### Dermal Absorption of OHM Via Drinking Water

Dermal absorption of oil or hazardous material may occur while the receptor is in contact with the contaminated drinking water. Everyday activities such as showering, bathing, washing floors and cooking lead to direct contact with water and may result in dermal absorption of the chemicals.

DEP/ORS has assessed the magnitude of the dermal exposure received during showering (Brown et al., 1984) and has evaluated this exposure relative to that which a receptor would be expected to receive from drinking the same water. For most

organic compounds, the shower/dermal absorption exposures are estimated to be approximately 20% (or less) than the estimated drinking water ingestion exposures (MADEP, 1992a). For chemicals which penetrate the skin the fastest (i.e., those with high permeability constants of approximately  $1 \text{ cm}^3/\text{cm}^2 \cdot \text{hr}$  or greater), the dermal doses received are roughly equivalent to the ingestion doses (Hutcheson, et al., in press). Based upon these observations, BWSC recommends that the following streamlined approach be adopted<sup>1</sup>:

- For the majority of organic compounds, the absorbed dermal dose may be approximated as 20% of the calculated dose received from drinking water ingestion:

$$ADD_{\text{dermal}} = 0.2 * ADD_{\text{ingestion}}$$

- For organic compounds which have a permeability constant greater than  $0.5 \text{ cm}^3/\text{cm}^2 \cdot \text{hr}$  (including ethylbenzene and toluene), the absorbed dermal dose may be approximated as the calculated dose received from drinking water ingestion:

$$ADD_{\text{dermal}} = ADD_{\text{ingestion}}$$

- For metals and inorganic compounds, the dermal exposures experienced during showering may be assumed to be negligible when compared with the exposures received while ingesting the contaminated water.

These approximations are considered protective for most chemicals, and when applied within the stated limitations, would be generally be acceptable to the BWSC. However, the approach is generic, and will yield less accurate dose estimates for some compounds than others. Therefore, as an alternative, the risk assessor may choose to explicitly calculate the dose received when the receptor comes into dermal contact with contaminated water. The equation presented under *Surface Water Exposures* may be used with assumptions appropriate to the specific exposure being modelled.

### Inhalation of OHM Volatilized from Drinking Water

As with the dermal exposures associated with the use of drinking water, numerous studies (Andelman, 1985; Foster and Chrostowski, 1987; McKone, 1987; McKone, 1991) have looked at the magnitude of the inhalation exposures associated with household water use. Based on a review of those studies, ORS has concluded that for

<sup>1</sup> These approaches assume 100% absorption via ingestion. The equation should be modified (dividing the ADD ingestion by the oral absorption efficiency) if less oral absorption is assumed to occur.  
 Example:  $ADD_{\text{dermal}} = 0.2 * ADD_{\text{ingestion}} \div \text{Oral Absorption Efficiency}$   
 Note that assuming lower oral absorption increases the fraction of the total dose attributable to dermal contact.

*volatile* organic compounds (i.e. compounds with a Henry's Law Constant equal to or greater than  $5 \times 10^{-4} \text{ atm} \cdot \text{m}^3/\text{mol} \cdot \text{K}$ ), the shower/inhalation exposures are likely to be approximately equal to and no greater than the estimated drinking water ingestion exposures. However, exposures to compounds with lower Henry's Law Constants are likely to be lower.

Based upon these observations, BWSC recommends that the following streamlined approach be adopted for the evaluation of shower/inhalation exposures:

- For chemicals with a Henry's Law constant equal to or greater than  $5 \times 10^{-4} \text{ atm} \cdot \text{m}^3/\text{mol} \cdot \text{K}$  (at 20→25°C), the applied dose (in mg/kg/day) received via inhalation may be approximated as the calculated applied dose received from drinking water ingestion (This value would correspond to the result of Equation 20 if the RAF factor were removed.)
- For chemicals with a Henry's Law constant less than  $5 \times 10^{-4}$  but greater than or equal to  $1 \times 10^{-5} \text{ atm} \cdot \text{m}^3/\text{mol} \cdot \text{K}$  (at 20→25°C), the applied dose (in mg/kg/day) received via inhalation may be approximated as one half the calculated applied dose received from drinking water ingestion (or  $\frac{1}{2}$  The value which would result from Equation 20 if the RAF factor were removed.)
- For chemicals with a Henry's Law constant less than  $1 \times 10^{-5} \text{ atm} \cdot \text{m}^3/\text{mol} \cdot \text{K}$  (at 20→25°C), the inhalation exposures experienced during showering are assumed to be negligible relative to the ingestion exposures and would not need to be evaluated unless the chemical under investigation is significantly more toxic when inhaled than when ingested.

Unlike the dermal exposures, however, it cannot be assumed that the chemicals have equal toxicity by inhalation and oral exposures. In order to estimate risk using the Reference Concentration or Unit Risk toxicity values, the doses approximated as above must be converted to an applied inhalation exposure (in concentration units such as  $\mu\text{g}/\text{m}^3$ ) using the following equation:

$$ADE_{\text{inhalation}} = \frac{ADD_{\text{inhalation}} * BW * C}{VR} \quad (7-21)$$

Where:

- $ADE_{\text{inh}}$  = The average daily exposure to the contaminant in air resulting from one shower exposure per day (dimensions: mass/volume; typical units:  $\mu\text{g}/\text{m}^3$ ).
- $ADD_{\text{inh}}$  = Average daily dose of OHM (ia inhalation) approximated from the water ingestion pathway (dimensions: mass/mass-time; typical units: mg/kg-day).

BW = Body weight of the receptor of concern during the averaging period (dimension: mass; typical units: kg).  
 C = Appropriate units conversion factor(s).  
 VR = Ventilation (inhalation) rate for the receptor of concern during the exposure event (dimensions: volume/time; typical units: m<sup>3</sup>/hr.)

NOTE: Equation 21 provides the calculation of an Average Daily Exposure. If the goal is to calculate the exposure point concentration during the shower event, Exposure Frequency and Exposure Duration terms should be inserted in the denominator of Equation 21:

EF = Exposure frequency. The number of shower events during the exposure period divided by the number of days in the exposure period. (Dimensions: events/time; typical units: event/day).  
 ED = Duration of shower exposure event (dimensions: time/event; typical units: minutes/event).

Alternatively, shower models available in the literature (Foster and Chrostowski, 1987) may be used to estimate chemical-specific air exposures.

#### 7.3.4.6 Surface Water

Contamination in surface water can result in receptor exposures from the incidental ingestion of the water, through dermal contact with the water, and through the inhalation of material volatilized from the water. As with the drinking water evaluation, the ingestion and dermal doses are assumed to be equitoxic and the estimated values may be mathematically combined:

$$ADD_{\text{oral, dermal}} = ADD_{\text{oral}} + ADD_{\text{dermal}} \quad (7-22)$$

The assumption of equitoxicity is not assumed to apply to the dose received via the inhalation of volatilized material from the water, and the risk associated with this exposure must be evaluated separately using appropriate toxicity information.

#### Surface Water Ingestion

The equation used to estimate the Average Daily Dose received by a receptor via the ingestion of contaminated surface water ( $ADD_{\text{surface water ingestion}}$ ) is identical to that used to evaluate drinking water ingestion exposures, which is described earlier in this section. The assumptions chosen to describe the exposure (the volume of water ingested, the duration of the exposure event, etc...) should be representative of the exposure scenario being modelled.

#### Surface Water, Dermal Contact

The Average Daily Dose of a chemical received via dermal absorption from surface water ( $ADD_{\text{dermal, water}}$ ) may be calculated using the following equation. This approach is recommended by BWSC for all chemicals when the dermal exposure is explicitly calculated.

$$ADD_{\text{dermal, water}} = \frac{[OHM]_{\text{water}} * SA * K_p * RAF * EF * ED * EP * C}{BW * AP} \quad (7-23)$$

Where:

ADD <sub>dermal</sub>	=	Average daily dose of oil or hazardous material associated with dermal contact exposure to contaminated water. In units: mg/kg/day.
[OHM] <sub>water</sub>	=	The concentration of contaminant in water which is contacting the skin during the exposure event. (Dimensions: mass/volume; typical units: µg/liter).
SA	=	Body surface area exposed to contaminated water during the exposure event. (dimensions: area; typical units: cm <sup>2</sup> ).
K <sub>p</sub>	=	Permeability Constant. (dimensions: volume/(time * area); typical units: cm <sup>3</sup> /(hr * cm <sup>2</sup> ), which is often simplified to cm/hr).
RAF	=	Relative Absorption Factor for dermal contact with water. Note: when the permeability constant (K <sub>p</sub> ) is used to determine the flux of contaminant through the skin, it results in an <u>absorbed</u> dose of OHM. The RAF is used here to adjust this absorbed dose to make it comparable to the toxicity value employed to estimate risk. The numerator of the RAF must be assigned a value of 1, and the denominator depends upon the absorption in the study which is the basis of the toxicity value (See Section 7.2.3). If the toxicity value itself is based on an <u>absorbed</u> dose, then the RAF <sub>dermal</sub> is 1 by definition. Dimensionless.
EF	=	The exposure frequency, or the number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time; typical units: events/day).
ED	=	The duration of each exposure event (dimensions: time/event; typical units: hours/event).
EP	=	Duration of exposure period (dimension: time; typical units: years).
C	=	Appropriate units conversion factor(s).
BW	=	Body weight of the receptor of concern during the averaging period (dimensions: mass; typical units: kg).
AP	=	Averaging Period (dimension: time; typical units: years).

Alternatively, another model, specific to organic compounds and assuming some exposure period before a steady-state condition is established, is described in a USEPA Interim Report (USEPA, 1992). The USEPA cautions in that document that this procedure is still under review by the scientific community and that further refinement of the approach is expected.

### Inhalation Exposures Associated With Contaminated Surface Water

Under some circumstances the volatilization of oil or hazardous material from surface water may contribute to exposure experienced by the receptor of concern. Such exposures are more likely to be of concern if the material is volatilizing into a confined space or if the concentrations in the surface water are relatively high. The exposures associated with this scenario may be evaluated following the equation presented in Section 7.3.4.1, with the [OHM]<sub>air</sub> term being either measured or modelled air concentrations of the contaminant.

#### 7.3.4.7 Food

The average daily dose ( $ADD_{\text{food}}$ ) experienced by the receptor as a result of consuming food (e.g. garden produce) containing oil or hazardous material may be estimated using the following equation. The general form of this equation may be applied to the ingestion of contaminated fish, meat, or vegetables. The evaluation of exposure to infants from ingesting mother's milk or other fluids may be estimated using the general equation for drinking water exposures in combination with the appropriate exposure factors.

$$ADD_{\text{food}} = \frac{[OHM]_{\text{food}} * FI * RAF * EF * ED * EP * C}{BW * AP} \quad (7-24)$$

Where:

- [OHM]<sub>food</sub> = Representative concentration of OHM in the food of concern during the period of exposure (dimensions: mass/mass, typical units: mg/kg)
- FI = Daily intake of the food of concern on days exposed during the exposure period (dimensions: mass/event; typical units: mg/meal)
- RAF = Bioavailability Adjustment Factor
- EF = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time, typical units: meals/day)
- ED = Duration of the exposure period (dimension: time, typical units: years)
- BW = Body weight of the receptor of concern during the averaging period (dimension: mass, typical units: kg)
- AP = Averaging Period (dimensions: time, typical units: years)
- C = Appropriate units conversion factor(s)

#### 7.3.4.8 Calculation of Lifetime Average Daily Dose (For All Media)

The lifetime average daily dose should be calculated to reflect age-related differences in exposure rates that are experienced by a receptor throughout his or her lifetime of exposure. Because of their low body weight and behavioral characteristics, young children receive greater exposure per unit body weight than older children and adults. Furthermore, young children typically have more dermal contact with soil and more hand-to mouth activity. Therefore, the LADD should be calculated in a way that does not "dilute" the higher exposure rates experienced by young children with lower exposure rates experienced by older children and adults.

For example, a LADD (based on a 30-year exposure period) which uses an average body weight and skin surface area value for all ages of receptor (1<31) will not be protective of the high exposure rates in young children and is not a recommended procedure.

There are a number of averaging methods that can be used to calculate a LADD that reflects the higher exposure rates experienced by young children. One method is to calculate average annual dose rates, normalized to body weight, for each year of exposure. The sum of the dose rates is then averaged over a lifetime (75 years). The equation below shows this averaging approach. However, this type of calculation can be tedious, even when performed by computer.

$$LADD = \frac{\sum_{i=0}^{30 \text{ years}} \frac{IR_i \times EP_i}{BW_i}}{AP} \quad (7-25)$$

Where:

- $IR_i$  = Average Intake rate for the exposure period (mg/day)
- $EP_i$  = Exposure period, one year
- $BW_i$  = Age-dependent body weight, ages 0 to 30
- $AP$  = Averaging Period, lifetime (75 years)

As an alternative, there is a simpler averaging approach which can be used to calculate the lifetime average daily dose. This simpler approach gives essentially the same results as the year-by-year averaging method. The simpler averaging approach uses a weighted average for younger children aged 1 to 6. Children aged 1 to 6 is a logical choice for the weighted group because the default soil ingestion rate for children aged 1 to 6 is 100 mg per day (double the rate used for older children and adults). Thus, children aged 1 to 6 have a much higher rate of exposure because of the higher rate of soil ingestion assumed.

As the equation below shows, only two Average Daily Doses need to be calculated instead of 30. This greatly simplifies the calculations. The Average Daily Dose for children aged 1 to 6 is calculated using average exposure parameters for children in this age group. Similarly, the Average Daily Dose for the receptors aged 6 to 31 is calculated using average values for receptors in this group. The LADD is then calculated as the sum of the two doses averaged over a lifetime. The equation below shows this weighted calculation.

$$LADD = \frac{\frac{IR_{1<6}}{BW_{1<6}} \times EP_1 + \frac{IR_{6<31}}{BW_{6<31}} \times EP_2}{AP} \quad (7-26)$$

Where:

$IR_{1<6}$  = Average Intake rate for receptors aged 1 to 6 (mg/day)  
 $EP_1$  = Exposure period, 5 years  
 $BW_{1<6}$  = Average body weight for children ages 1 to 6  
 $IR_{6<31}$  = Average Intake rate for receptors aged 6 to 31 (mg/day)  
 $EP_2$  = Exposure period, 25 years  
 $BW_{6<31}$  = Average body weight for receptors aged 6 to 31  
 $AP$  = Averaging Period, lifetime (75 years)

As stated above, this weighted average approach can be used to calculate the LADD and will result in essentially the same results as the more complicated year-by-year averaging approach.

## 7.4 RISK CHARACTERIZATION

Risk Characterization is the final step in the risk assessment process. In this step, the results of the Hazard Identification, Dose-Response Assessment and Exposure Assessment are integrated to yield quantitative measures of cancer and noncancer risk. The Risk Characterization can be thought of as providing a link between risk assessment and risk management because it presents the numerical estimates of risk posed by the site in a context that can be used easily by risk managers to make decisions about remediation. In accordance with the MCP (310 CMR 40.0993(6)), the Risk Characterization step must also must include a comparison of Exposure Point Concentrations (EPCs) with applicable or suitably analogous public health standards.

A critical component in the presentation of risk estimates is the discussion of major assumptions, scientific judgements and uncertainties inherent in the numerical risk estimates. The importance of this component cannot be overstated. The discussion of uncertainties should place the numerical estimates of risk and hazard in the overall context of what is known about the site and what is uncertain. The numerical risk estimates should never be interpreted as a characterization of absolute risk but should always be interpreted in the context of the uncertainties.

The regulations provide clear direction regarding the way numerical estimates of risk are to be presented in the Risk Characterization (310 CMR 40.0933). The MCP requires that chemical-specific and medium-specific estimates of risk be combined to yield Cumulative

Cancer and Noncancer Risks for each Receptor. These Cumulative Risks are then compared with specific risk management criteria which include public health standards and Cumulative Receptor Risk Limits (310 CMR 40.0933(6)). The result of this comparison determines whether a condition of No Significant Risk of harm to human health exists or has been achieved at the site.

This Section of the *Guidance* describes methods for characterizing cancer and noncancer risks and discusses the interpretation of Risk Characterization results within the context of the MCP. This Section also addresses the identification of Applicable or Suitably Analogous Public Health Standards and the comparison of such standards with EPCs. Lastly, this Section addresses how uncertainties in the Risk Assessment should be addressed.

#### 7.4.1 Noncancer Risk

The measure used to describe the potential for noncarcinogenic health effects is the Hazard Index (HI). For a given chemical, the HI is the ratio of a receptor's exposure level (or dose) to the "acceptable" (or allowable) exposure level. A Hazard Index of 1.0 or less indicates that the receptor's exposure is equal to or less than the allowable exposure level, and it is considered unlikely that adverse health effects will occur. When the HI is less than or equal to 1.0, a conclusion of "No Significant Risk of harm to human health" based on non-cancer effects, is appropriate.

A HI of greater than 1.0 indicates that noncancer health effects could occur, and cannot be ruled out. It does not mean that noncancer effects will occur. Uncertainty inherent in most Reference Doses precludes identifying a specific dose above which adverse effects are likely and below which effects are unlikely. Accordingly, the probability of an effect cannot be quantified from a HI. For any one chemical, it is always true that the likelihood of an effect increases as the exposure level (and therefore the HI) increases.

The uncertainty inherent in RfDs for different chemicals differs both qualitatively and quantitatively. Therefore, for different substances, the probability of an effect increases at different rates. For example, a HI of 20 for one substance may indicate a very high probability of an effect, but may represent only a moderate probability of an effect for another chemical.

In interpreting the HI, one must consider the appropriateness of the exposure assumptions and the basis of the toxicity information used to develop the RfD. As a general rule, the greater the HI is above 1.0, the greater the level of concern.

In its most general form, the Hazard Index associated with a chemical via a given route of exposure is calculated as:

$$HI = \frac{ADD}{RfD} \quad (7-27)$$

or, for inhalation exposures,

$$HI = \frac{[OHM]_{air}}{RfC} \quad (7-28)$$

Where:

HI =	The <u>H</u> azard <u>I</u> ndex associated with exposure to the chemical via the specified route of exposure.
ADD =	The estimated <u>A</u> verage <u>D</u> aily <u>D</u> ose of the chemical via the specified exposure route. In mg/kg/day.
RfD =	The oral <u>R</u> eference <u>D</u> ose or appropriate substitute toxicity value identified for the chemical of concern. In mg/kg/day.
[OHM] <sub>air</sub> =	The <u>E</u> xposure Point Concentration of the <u>O</u> il or <u>H</u> azardous <u>M</u> aterial in <u>a</u> ir. In µg/m <sup>3</sup> .
RfC =	The <u>R</u> eference <u>C</u> oncentration or substitute toxicity value identified for the chemical of concern. In µg/m <sup>3</sup> .

The Average Daily Dose (ADD) in equation 7-27 is calculated from the Exposure Point Concentration using exposure assumptions consistent with the Exposure Profiles developed for each receptor being evaluated. Section 7.3 of this Guidance describes the process for calculating a receptor's ADD.

The allowable dose or exposure (denominators in equations 7-27 and 7-28) will typically be the EPA Reference Dose (RfD) for most exposure routes or the EPA Reference Concentration (RfC) for air exposures. Selection of an appropriate "acceptable" dose is discussed in Section 7.2.

It is important to calculate separate HIs for acute, subchronic or chronic exposures if these have been identified as exposure periods of concern in the development of exposure profiles.

As mentioned previously, the MCP requires that cumulative noncancer risks be calculated. A cumulative HI represents the cumulative noncarcinogenic impact that the site has on a particular receptor group. The cumulative HI accounts for exposures that a receptor may receive from multiple chemicals and multiple exposure routes.

Again, remember that separate cumulative HIs are calculated for acute, subchronic or chronic exposures that have been identified as exposure period of concern for the site.

As shown by the following two equations, the cumulative HI can be calculated by summing the exposure route-specific HI. Route specific HI are calculated as the sum of all chemical-specific HIs.

$$Total HI_{route-specific} = \sum HI_{chemical-specific} \quad (7-29)$$

$$Cumulative HI = \sum HI_{route-specific} \quad (7-30)$$

If the risk calculations are being performed using a probabilistic analysis, the risk assessor must identify the dose or concentration associated with the 95<sup>th</sup> percentile estimate of exposure (310 CMR 0993(5)). This dose or concentration should be compared with the toxicity value identified following the dose/response section of this Guidance. This HI is then compared with the HI Limit of 1.0 in order to determine whether the site poses a significant risk of harm to human health based on the risk of noncancer health effects.

The documentation of the Risk Characterization must clearly present all mathematical equations used to calculate Cumulative Noncancer Risks (310 CMR 40.0993(9)).

#### 7.4.1.1 Screening Hazard Index

Initially, the risk assessor should use equation 7-30 above to calculate a Screening Hazard Index for a given receptor group based on all chemicals of concern at the site in all exposure routes at all exposure points. A HI calculated in this way will provide a conservative estimate of the true HI because it treats as additive, different toxic effects from multiple chemicals acting on different organ systems by different mechanisms of action. In fact, in a true HI, the only endpoints which should be treated as additive are those which produce adverse effects on the same organ system by the same mechanism. Thus, the Screening HI will provide a conservative estimate of the actual HI because it reflects the sum of toxicities for multiple chemicals, regardless of the chemical's health endpoint, target organ or mechanism of action.

Recall that there may be multiple adverse health effects associated with exposure to a given chemical and it is the most sensitive adverse health effect observed in the scientific data which drives estimation of the Reference Dose. Thus, for a given group of chemicals, Reference Doses may be based on a different toxic effects on different organ systems by different mechanisms of action.

The screening HI should be compared with the MCP Cumulative Receptor Noncancer Risk Limit which is a HI equal to 1.0 (310 CMR 40.0933(6)). If the screening HI is less than 1.0, then no additional effort is needed to characterize noncancer risks. However, if the screening HI exceeds 1.0, the risk assessor should then calculate separate HIs for chemicals with similar toxic effects and mechanisms of action.

Remember that separate screening HIs should be calculated for different exposure periods (i.e., chronic, subchronic, acute).

#### **7.4.1.2 Health Endpoint-Specific Hazard Index**

The procedure for segregating HIs by effect and mechanism of action is not simple and should be performed by a toxicologist. If the segregation is done improperly, an underestimate of the true hazard could result. Segregation of HIs requires identification of the major health endpoints of each chemical, including effects observed at higher doses than the critical effect on which the toxicity value is based. This is because the critical effect for one chemical may not be relevant for other chemicals and doses of other chemicals may not be additive for that effect. On the other hand, additive impacts could be important for other health endpoints that are only expected at higher doses.

Major effect categories that should be considered in segregating chemicals include neurotoxicity, developmental toxicity, reproductive toxicity and immunotoxicity. Adverse effects also should be categorized by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal and dermal/ocular). The effects and mechanism of action should be discussed in the toxicological profile.

Once chemicals have been categorized, the Cumulative Hazard Index for chemicals with similar health endpoints and mechanisms of toxicity should be calculated. Each HI should be compared with the MCP Cumulative Receptor Noncancer Risk Limit which is a HI equal to 1.0. If any of the HIs exceeds one, then the Risk Characterization must conclude that the site poses Significant Risk of harm to human health based on the risk of noncancer health effects.

#### **7.4.2 Cancer Risk**

The potential for carcinogenic (i.e., nonthreshold) health effects is characterized as the Excess Lifetime Cancer Risk (ELCR). The ELCR represents the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen. For a given chemical, the estimated ELCR is the product of the receptor's quantified exposure and a measure of carcinogenic potency. The typical measures of carcinogenic potency are the EPA Cancer Slope Factor (SF) for most exposure routes and the Unit Risk (UR) for inhalation.

In its basic form, the ELCR associated with exposure to a given chemical via a particular exposure pathway is estimated as follows:

$$ELCR = LADD \times SF \quad (7-31)$$

or, for inhalation exposures,

$$ELCR = [OHM]_{air} \times UR \quad (7-32)$$

Where:

- ELCR = The Excess Lifetime Cancer Risk associated with exposure to the chemical via the specified route of exposure.
- LADD = The estimated Lifetime Average Daily Dose of the chemical via the specified exposure route. In mg/kg/day.
- SF = The Cancer Slope Factor identified for the chemical, appropriate to the specific exposure pathway. In (mg/kg/day)<sup>-1</sup>. The selection of this toxicity value is discussed in Section 7.2.2 of this Guidance.
- [OHM]<sub>air</sub> = The Exposure Point Concentration of the Oil or Hazardous Material in air. In µg/m<sup>3</sup>.
- UR = The Unit Risk for the particular chemical of concern. In µg/m<sup>3</sup>. The identification and selection of UR values is described in Section 7.2.2.

The Lifetime Average Daily Dose (LADD) in equation 7-31 is calculated from the Exposure Point Concentration using exposure assumptions consistent with the Exposure Profiles developed for each receptor being evaluated. Section 7.3 of this Guidance describes the process for calculating a receptor's LADD. The selection of Cancer Slope Factors and Unit Risk values is discussed in greater detail in Section 7.2.2.

As mentioned previously, the MCP requires that cumulative cancer risks be calculated. The cumulative cancer risk must be estimated for all Class A and B carcinogens (i.e., chemicals classified by EPA as being known human carcinogens and probable human carcinogens). For most Class C Carcinogens (i.e., those classified by EPA as being possible human carcinogens), the available toxicity data is insufficient to quantify cancer risks. In general, potential carcinogenic effects of these substances should be discussed qualitatively in the Uncertainty Section of the Risk Assessment. However, the Department may in the future identify some Class C carcinogens for which there is sufficient data to include these substances in the quantitative assessment of carcinogenic risk.

The cumulative ELCR represents the cumulative carcinogenic impact that the site has on a particular receptor group. The cumulative ELCR accounts for exposures that a receptor may receive from multiple chemicals and multiple exposure routes.

As shown by the following two equations, the cumulative ELCR can be calculated by summing all of the exposure route-specific ELCRs. Route-specific ELCRs are calculated as the sum all the chemical-specific ELCRs.

This is represented by the following equations:

$$Total ELCR_{route-specific} = \sum ELCR_{chemical-specific} \quad (7-33)$$

$$Cumulative ELCR = \sum ELCR_{route-specific} \quad (7-34)$$

The Cumulative ELCR should be compared with the MCP Cumulative Receptor Cancer Risk Limit which is an ELCR equal to one-in-one hundred thousand ( $1 \times 10^{-5}$ ). If the Cumulative Cancer Risk exceeds the ELCR Limit then the Risk Characterization must conclude that the site poses significant risk of harm to human health based on the risk of cancer health effects.

If the risk calculations are being performed using a probabilistic analysis, the risk assessor must identify the dose or concentration associated with the 95<sup>th</sup> percentile estimate of exposure (310 CMR 0993(5)). This dose or concentration should be compared with the toxicity value identified following the dose/response section of this Guidance. This ELCR is then compared with the Cancer Risk Limit of  $1 \times 10^{-5}$  in order to determine whether the site poses a significant risk of harm to human health based on the risk of cancer health effects.

The documentation of the Risk Characterization must clearly present all mathematical equations used to calculate Cumulative Cancer Risks (310 CMR 40.0993(9)).

### 7.4.3 Comparison to Applicable or Suitably Analogous Public Health Standards

The MCP requires that the characterization of risk of harm to human health include a comparison of EPCs to applicable or suitably analogous public health standards. The list of such standards, as provided in the MCP includes, but is not limited to:

- Massachusetts Drinking Water Quality Standards, promulgated in 310 CMR 22.00 (*these standards are considered applicable only to category GW-1 groundwater*).
- Massachusetts Air Quality Standards promulgated in 310 CMR 6.00; and
- Massachusetts Surface Water Quality Standards promulgated in 314 CMR 4.00.

It should be noted that the MCP Method 1 Soil and Groundwater Standards listed in 310 CMR 40.0970 are not considered applicable or suitably analogous, as those standards represent an alternative risk characterization approach to Method 3. MADEP staff have noted a tendency to include a list of the Method 1 standards in Method 3 risk

characterizations, but including those standards only confuses the reader and brings into question how the risks were actually characterized.

As provided in the MCP, if any EPC exceeds an applicable or suitably analogous standard, the Risk Characterization must conclude that a condition of Significant Risk exists at the site.

#### **7.4.4 Risk Characterization Conclusions**

The documentation of the Method 3 Human Health Risk Characterization must contain a clear statement of whether or not a condition of No Significant Risk of harm to human health exists or has been achieved, based upon the criteria contained at 310 CMR 40.0993(7).

As provided in the MCP, a condition of No Significant Risk of harm to human health exists or has been achieved at the site if:

- no Exposure Point Concentration of oil or hazardous material is greater than an applicable or suitably analogous public health standard; AND
- no Cumulative Receptor Cancer Risk calculated is greater than the Cumulative Cancer Risk Limit; AND
- no Cumulative Receptor Noncancer risk is greater than the Cumulative Receptor Noncancer Risk Limit.

Note that all three criteria must be met in order for a conclusion to be reached that the site poses No Significant Risk of harm to human health.

### **7.5 UNCERTAINTY ANALYSIS**

The Uncertainty Analysis is a critical component of the Risk Characterization. The Uncertainty Analysis should contain a narrative section which places the numerical risk estimates in the overall context of what is known and what is not known about the site and in the context of decisions that the site manager will make about remediation. The Uncertainty Analysis does not modify the risk characterization conclusions themselves. However, a Risk Characterization is not considered complete unless the numerical risk estimates are accompanied by an explanation which interprets and qualifies the risk results.

Inherent in all risk assessments are many assumptions, scientific judgements and a wide variety of uncertainties, which can be introduced at each step in the risk assessment process. In addition, dose response and exposure assessment guidance presented in this document are

intended to produce conservative, consistent estimates of the potential for adverse impacts. For all of these reasons, the numerical risk estimates calculated in the Risk Characterization should never be interpreted as absolute, purely scientific estimates of the risk of harm to health.

General sources of uncertainty in the risk assessment which should be discussed in the Uncertainty Analysis include, but are not limited to:

- Identification of all site-related contaminants in sampling of the environmental media at the site.
- Modeling used to develop Exposure Point Concentrations.
- Quantitative toxicological data used to develop cancer and noncancer toxicity values.
- Development of Exposure Profiles and selection of exposure assumptions used in dose calculations.

Although the Uncertainty Analysis may be a qualitative evaluation of uncertainties affecting the risk estimates, the risk assessor should attempt to describe the magnitude and direction of effect that a particular area of uncertainty is likely to have on the numerical risk estimates.

Monte Carlo Analysis can be a powerful tool for expressing the uncertainties in risk assessments. The reader should refer to Appendix C for a discussion about the use of Monte Carlo Analysis.

## 7.6 SHORTCUTS

Under certain circumstances, it may be possible to substantially reduce the level of effort necessary to conduct a Method 3 risk assessment. Two possible shortcuts, the "Screening" Risk Characterization and the *DEP Risk Assessment ShortForm - Residential Scenario* are specifically discussed.

Other shortcuts, if they are logical, clearly identified and defensible (usually with a quantitative demonstration) may be used as well and are encouraged. Using a shortcut without adequate justification is inappropriate.

### 7.6.1 Screening Risk Characterization

One shortcut option that may be considered is to conduct a "Screening" Human Health Risk Characterization using worst-case exposure assumptions (310 CMR 40.0902(5)). The objective of a screening evaluation is to quickly demonstrate that a condition of No Significant Risk exists or has been achieved at a disposal site. To do this, the risk assessor should use worst-case exposure assumptions and conservative toxicity values. For example, the risk assessor might assign the toxicity value for the most toxic substance at a site to all substances at the site and use the maximum reported concentration for each chemical as the EPC. Assuming residential exposures at an industrial site is another possible overly-conservative assumption that may be used in a screening risk characterization.

The objective of the screening risk characterization is to save time and money by using readily available data and information that will result in risk estimates that will not underestimate the risks posed by the disposal site. Thus, if the resulting risks are below the MCP Risk Limits, clearly, remediation would not be required based on risk of harm to human health. It is important to note that remediation may still be required based on risk of harm to the environment, public welfare or safety.

A screening risk characterization may also be used to demonstrate that certain exposure pathways result in risks which are trivial, compared with the MCP Cumulative Risk Limits. Such a demonstration would justify the elimination of that exposure pathway from consideration in the risk characterization. In general, "trivial" is considered as being a level of risk that is at least one order of magnitude smaller than the MCP Risk Limit, based on a conservative risk characterization as described in the preceding paragraphs.

A screening risk characterization is intended as an option to reduce the cost and level of effort involved in conducting a risk characterization, not site characterization. The results of a "Screening" risk characterization should never be used to justify inadequate site characterization.

### 7.6.2 DEP Risk Assessment ShortForm - Residential Scenario

The *Residential ShortForm* is an optional tool which has been developed by the Department to provide a streamlined method of evaluating potential human health risks at 21e sites. The *ShortForm* streamlines the process by providing a rapid, low cost procedure for assessing health risks. The *ShortForm* is a *LOTUS 1-2-3* (or *Quattro Pro*) spreadsheet incorporating standard assumptions for assessing residential exposures and equations which are used to estimate human health cancer and noncancer risks. The *ShortForm* is intended for use at "residential" sites which are to be evaluated via a Method 3 risk assessment. The output of the *Residential ShortForm* is a series of summary tables which describe the EPCs, toxicity information and potential chemical-specific, medium-specific and cumulative health risks. These output tables can be submitted as the Risk Assessment portion of a Phase II Report.

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## **8.0 METHOD 3 - PUBLIC WELFARE**

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A Draft of this Section is expected to be available in the fall of 1995.

Copies of the Public Welfare Risk Characterization Guidance will be available through the MADEP Bulletin Board System and through the MADEP InfoLine/MCP Hotline.

Please call the MCP Hotline for the latest information on the schedule for this guidance.

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## 9.0 METHOD 3 - ENVIRONMENTAL RISK CHARACTERIZATION

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A Draft of this Section is expected to be available in the fall of 1995.

Copies of the Environmental Risk Characterization Guidance will be available through the MADEP Bulletin Board System and through the State Bookstore.

Please call the MCP Hotline for the latest information on the schedule for this guidance.

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## 10.0 IMMINENT HAZARD EVALUATIONS

One of the purposes of risk characterization under the Massachusetts Contingency Plan is to identify and evaluate site conditions which may pose an *Imminent Hazard*. As defined in the MCP, an Imminent Hazard means a hazard which would pose a significant risk of harm to health, safety, public welfare or the environment if it were present for even a short period of time (310 CMR 40.0006). This section of the *Guidance for Disposal Site Risk Characterization* describes the process by which site conditions may be assessed to determine whether or not an Imminent Hazard exists.

*The MCP contains detailed procedures for identifying and evaluating Imminent Hazards. However, it must be stressed that the overriding objective of the Imminent Hazard provisions in the MCP is to ensure that response actions will be taken quickly to prevent or abate exposures that pose an imminent hazard. The risk assessor should keep this objective in mind when reading this section of the Guidance. Taking a response action that addresses ongoing exposures right away is always preferable to conducting an evaluation to determine whether the exposures actually pose an imminent hazard.*

The MCP describes a risk characterization methodology to be followed when evaluating imminent hazards (310 CMR 40.0950). This methodology is site-specific in nature, and focuses on *actual, or likely exposures* under current site conditions, given the *current site use(s) and site activities* and the surrounding environment, and considering a *short exposure period*. The MCP also includes specific risk limits for imminent hazards (310 CMR 40.0955(2)(b)). The important distinctions between a risk characterization for an imminent hazard evaluation and a risk characterization for purposes of a Response Action Outcome (RAO) is that the imminent hazard evaluation is much narrower in scope, it need only consider actual, current exposures, given current site use(s) and not foreseeable future use(s) and exposures. In addition, the imminent hazard evaluation often focuses on only those chemicals that are most likely to pose a risk following short-term exposures, given their toxicity and site concentrations.

If the results of an imminent hazard evaluation indicate that conditions at the site pose an imminent hazard, the MCP requires that an Immediate Response Action (IRA) be taken to address the hazard. However, recall that one always has the option to take a response action to address a potential imminent hazard rather than conducting an evaluation to determine whether the conditions do indeed pose an imminent hazard. In fact, for any release which a project manager believes is likely to pose an imminent hazard, the Department recommends taking immediate action to address the release rather than conducting an evaluation to confirm whether or not it is an imminent hazard.

The MCP provides that Imminent Hazard Evaluations be conducted separately for safety, human health and the environment, depending on the type of condition that triggered the need for the evaluation. This is because for different types of imminent hazards, the situation leading to the imminent hazard condition and the information needed to evaluate the condition may be different.

*For example, the presence of insecurely containerized OHM may pose an Imminent Hazard to Safety and may also pose an Imminent Hazard to Human Health. Safety and Human Health issues should be assessed separately. However, if it is concluded that conditions pose an Imminent Hazard to Safety, it would not be necessary to additionally evaluate whether those same conditions pose an Imminent Hazard to Human Health.*

### **10.1 Deciding Whether an Imminent Hazard Evaluation is Necessary**

The MCP does not define specific situations or conditions at a site which trigger an imminent hazard evaluation. Rather, the regulations describe general factors that must be considered in the decision about whether to conduct an imminent hazard evaluation and rely on the application of professional judgement to determine when site conditions warrant such an evaluation. Since Imminent Hazards can occur at any point in the MCP process, the project manager should be mindful throughout all phases of site investigation and remediation of the possibility that information indicating a potential imminent hazard will come to light.

The MCP 40.0951(1) prescribes that the decision to conduct an Imminent Hazard Evaluation must consider the location and nature of the oil and/or hazardous material and the human or environmental receptors which may be exposed. It is important to keep in mind that when deciding whether an imminent hazard evaluation is needed, that exposures must be actually occurring (or very likely to occur) in order for an imminent hazard to exist.

An Imminent Hazard Evaluation should be considered whenever actual (or likely) exposures to contamination at a site are occurring, such as when people are drinking contaminated water or when there is surficial soil contamination in an area where children are present, such as a playground. The risk assessor should also give thought to the types of contaminants to which people are being exposed. Chemicals which can cause a severe effect after a one-time exposure, such as cyanide, certainly warrant consideration as a possible imminent hazard.

In deciding whether a given situation warrants further investigation as a potential imminent hazard, it may also be helpful to consider the following.

The Direct Contact soil standards in Table 5 of the MCP (310 CMR 0985(6)) were developed using noncancer and cancer risk management criteria ( $HI = 0.2$ ,  $ELCR = 1 \times 10^{-6}$ , respectively) that are roughly ten times lower than the risk management criteria used to evaluate whether risks experienced over a "*short period of time*" pose an imminent hazard. Risk assessors can use this knowledge, along with an understanding of how those standards were developed, to identify soil concentrations which may warrant further evaluation (i.e., multiples of the Table 5 values can be used as a "*rule-of-thumb*").

The Table 5 soil standards consider risks from direct contact (dermal contact and ingestion) with soil. Given this, multiples of the Direct Contact soil standards can be used as a general indicator of a situation which may warrant further investigation as a possible imminent hazard. For example, if a contaminant is present in surficial soil in an area where people are being exposed and the concentration of the chemical is greater than ten times the Table 5 standard for the applicable soil category, additional investigation may be warranted to determine whether the situation poses an imminent hazard. If the contamination is in an area where children are being exposed such as a schoolyard or ballfield, the comparison should be made using a multiple of the soil category S-1 value in Table 5, since the S-1 standards focus on exposures to children.

Used in this way, the Table 5 soil standards can provide a general indication to the risk assessor or project manager as to when site concentrations are approaching levels which could pose an imminent hazard. However, it is important to understand that the presence of a chemical at levels greater than ten times the Table 5 standard does not indicate that there is definitely an imminent hazard or even that there is likely an imminent hazard. It simply suggests that the situation may warrant further investigation. Because the Direct Contact soil standards incorporate considerations in addition to risk, a site-specific evaluation, even a very cursory one, may be all that is needed to rule out the possibility of an imminent hazard.

#### *Two-Hour Release Notification Requirements in Subpart C of the MCP*

It should also be noted that Subpart C of the MCP (310 CMR 40.0321) describes site conditions which require notification to DEP within 2 hours because they pose or could pose an imminent hazard. However, for some of these reportable releases, the existence of an Imminent Hazard is a rebuttable presumption (310 CMR 40.0321(2) and (3)).

In other words, a site-specific imminent hazard evaluation performed in a manner consistent with the Imminent Hazard risk characterization procedures in 310 CMR 40.0950 may be part of the Immediate Response Action (IRA) conducted following notification. In fact, such an imminent hazard risk characterization may show that further response actions are not necessary in the short term.

Any of the three sets of conditions described in 310 CMR 40.0321(2) and (3) trigger the two-hour release notification obligations in Subpart C of the MCP based on the presumption that they pose an imminent hazard to human health.

However, as stated above, a site-specific risk characterization may be conducted to demonstrate to the Department, that conditions at the site do not constitute an actual Imminent Hazard.

**310 CMR 40.0321(2)(b):**

a release indicated by the measurement of any of the trigger concentrations listed below within the top six inches of ground surface, at any location within 500 feet of a residential dwelling, school playground, recreational area or park, unless access to children is controlled or prevented by pavement, concrete, a fence, or other physical barrier. *Note: the revised MCP regulations limit this provision by specifying preventing access to children.*

	Concentration ( <u>µg/g dry wt</u> )
Arsenic (total)	40
Cadmium (total)	60
Chromium (VI)	10,000
Cyanide (available)	100
Mercury (total)	300
Methyl Mercury	10
PCB (total)	10

**310 CMR 40.0321(2)(a):**

a release indicated by the measurement of OHM in a private drinking water supply well at a concentration equal to or greater than ten times the Category RCGW-1 Reportable Concentration.

**310 CMR 40.0321(3):**

a threat of release which, were it to occur, is likely to meet any of the two-hour reportable releases that pose or could pose an Imminent Hazard.

***Development of Soil Concentrations Which Trigger Two-Hour Notification***

The soil concentrations in Subpart C which trigger two-hour notification are set generically to be protective under most exposure conditions. As such, the concentrations are used to "screen in" conditions which may require further assessment or remedial action in the short-term. These trigger levels cannot be used to definitively "screen out" a disposal site, as

it is possible (under more extreme exposure conditions) that concentrations below these levels could pose an imminent hazard. A site-specific assessment may conclude that the conditions at a disposal site pose an Imminent Hazard at concentrations which are higher or lower than those presented in the regulations.

The approach used to derive the Imminent Hazard Soil Trigger Levels follows the risk characterization procedures for Imminent Hazards detailed in the MCP. These procedures are discussed in detail in the remainder of this Section of the Guidance.

The Imminent Hazard Trigger Levels in Subpart C were identified through the evaluation of both cancer and non-cancer risks: the lower of the two estimated concentrations is chosen to be the Trigger Level in order to be protective of both types of health effect. The cancer and noncancer risk limits used in deriving the Trigger Values are the numerical Imminent Hazard Risk Limits specified in the MCP. These risk limits are discussed in detail in Section 10.2.4.

In evaluating cancer and noncancer risks, it was assumed that exposure would occur through dermal contact and ingestion of soil. Since the trigger levels are applicable in areas where it is likely that children will have frequent exposure to surficial soil (for example, in a schoolyard, playground or residential backyard), the exposure scenario evaluated in developing the Trigger Levels is thus analogous to a residential exposure scenario.

Since young children generally experience higher rates of exposure due to the nature of their activities and their low body weights, the evaluation of noncancer risks focused on a child aged 5-6 years old exposed during the summer months (June through August) when frequent contact with soil is likely. For cancer risks, the evaluation focused on the ages of 0 to 30 years. Exposure to contaminated soil was assumed to vary by age and time of year. For more detailed information including the exposure assumptions and equations used to calculate the Imminent Hazard Trigger Levels, the reader should refer to Appendix D of the *Background Documentation for Derivation of the Method 1 Standards* (April, 1994).

## 10.2 IMMINENT HAZARD EVALUATIONS FOR HUMAN HEALTH

The MCP requires that the Imminent Hazard risk characterization be conducted following the general procedures for a Method 3 risk assessment. As in a full scale risk characterization, the basic approach to be taken in an imminent hazard evaluation is to conduct an assessment that is realistic and health protective. The MCP prescribes that the Imminent Hazard Evaluation shall be conducted in a manner which results in conservative estimates of potential exposures (310 CMR 40.0953(9)). However, it is not the Department's intent that the Imminent Hazard Evaluation be as comprehensive as a Method 3 risk characterization conducted for purposes of an RAO. Rather, the intent is that an Imminent Hazard Evaluation be site-specific in nature. In fact, an Imminent Hazard risk characterization will typically be a much more streamlined evaluation than a full Method 3 risk assessment, because *future* uses and exposures need not be considered in the imminent hazard evaluation. In addition, conducting an Imminent Hazard evaluation using Method 3 does not preclude the use of a Method 1 or 2 risk assessment for the site as a whole.

As required in (310 CMR 40.0953(10), the documentation of the Imminent Hazard Evaluation must clearly identify and explain the basis for all exposure parameters chosen for the risk characterization.

### 10.2.1 Contaminants of Concern

In accordance with the MCP, the imminent hazard evaluation may be limited to those chemicals which are likely to dominate the risk estimates based upon their toxicity and concentration. A chemical may be eliminated from the Imminent Hazard Evaluation based upon a determination that it is not likely to contribute significantly to risks. EPA's concentration-toxicity screen, as described in the *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A)*, December 1989, Section 5.9.5 is a screening procedure which may be used to eliminate chemicals from the imminent hazard evaluation. However, if imminent hazards to the environment are being evaluated, chemicals should not be screened out based on toxicity to human health.

*Note that in the full risk characterization for a site, such use of toxicity screening to eliminate chemicals from the risk assessment should not be used (refer to Section 2.4 of this guidance manual).*

### 10.2.2 Exposure Assessment

#### Current Use(s)

The MCP specifies that the focus of an Imminent Hazard Evaluation is on actual or likely exposures to human and environmental receptors under current site conditions, considering the current use(s) of the site.

Thus, exposure profiles should be developed for each receptor identified for the current uses and activities at the site, under current site conditions. For example, if the site is currently an industrial property, then residential exposures need not be evaluated in the imminent hazard evaluation, even if the property may become residential in the future. Similarly, if the site is a residential property where only adults currently reside and there is no evidence that children visit the residential property, then exposures to children need not be evaluated in the imminent hazard evaluation.

Note that this differs from the way current activities and uses must be evaluated for the full risk assessment. In the full risk assessment, activities which are not occurring at the time of the assessment, but are consistent with the current use of the site must be evaluated. For example, in the full risk assessment, exposures to children at a residential property would need to be evaluated even if no children currently resided at the property because the presence of children is consistent with a residential use. This is another

example of how an Imminent Hazard Evaluation is more limited in scope than the risk characterization used to support an RAO.

As in a full risk characterization, the imminent hazard evaluation should identify the receptor group(s) experiencing the greatest exposure potential or susceptibility to environmental contamination. Young children and women of child-bearing age are often selected as receptors of concern because of these factors. The risk assessor may need to evaluate several receptor groups to ensure that all sensitive subpopulations are being protected. Conversely, the fact that the most sensitive receptors are being evaluated means that other (less exposed) receptors need not be evaluated.

### Exposure Duration

The exposure duration is the length of time over which the receptor comes into contact with the OHM. The MCP provides that the imminent hazard evaluation must focus on exposures over an appropriate "short period of time". The MCP defines a "short period of time" as any time period from the beginning of an exposure to five years. The MCP also provides that a "short period of time" may be greater than five years if exposures at the site have been ongoing for more than five years or if the response action will not be complete for a period of time greater than five years into the future (310 CMR 40.0953(1)).

In other words, the "short period of time" which is the focus of an Imminent Hazard Evaluation may in fact be much longer than a period of five years. The determination of what constitutes an appropriate "short period of time" for a particular site must consider how long exposures have already been occurring and when it is expected that final remedial action will be complete at the site.

*It should be noted that if, for instance, the appropriate "short period of time" at a site is 10 years (because exposures at that site have been ongoing for 10 years), this does not preclude the obligation to also evaluate appropriate shorter exposure periods such as acute (one-day) exposures or subchronic exposures. For example, if the chemical being evaluated is associated with severe effects which can occur from a single exposure (for example, cyanide), the imminent hazard evaluation should include an evaluation of a one-day exposure, as well as appropriate longer term exposures.*

*Note that it would be very rare for a contaminant other than cyanide to pose an acute risk. This is because for hazardous chemicals other than cyanide, the concentrations at which acute exposures are of concern are much higher than levels typically found at disposal sites.*

When evaluating potential cancer risks in an Imminent Hazard Evaluation, the MCP provides the risk assessor additional flexibility. In evaluating carcinogens, the risk assessor may choose to evaluate a long-term exposure (typically 30 years), rather than a shorter period, even if exposures at the site have actually been ongoing for a period less than a lifetime. The MCP provides this flexibility because the risk characterization used to support an RAO typically evaluates long-term exposures and because it is useful to be able to use the results of a long-term evaluation to make Imminent Hazard decisions. This can eliminate the need for new calculations in order to evaluate a potential imminent hazard. If a long-term exposure is assessed for carcinogens, the risk assessor can use a different risk management criterion in determining whether an Imminent Hazard exists. The selection of appropriate risk management criteria is discussed in greater detail in Section 10.2.4.

In summary, the imminent hazard evaluation should evaluate an exposure period that is appropriate considering the toxicity of the chemical(s) present at the site, what is known about how long exposures have been occurring and how long exposures are expected to continue. Depending on the site-specific situation, it may be appropriate to evaluate exposure periods longer than 5 years, shorter than five years, *or both*.

#### **Exposure Points and Exposure Point Concentrations**

The MCP contains several provisions about defining exposure points and estimating Exposure Point Concentrations (EPCs) for an imminent hazard evaluation.

Because the focus of an imminent hazard evaluation is on actual exposures and current site uses and activities, the evaluation of soil-related exposures may be limited to contamination in the accessible surface soil. The MCP defines this as soil to a depth of six inches (310 CMR 40.0953(4)). Thus, when estimating an EPC for soil in an imminent hazard evaluation, chemicals present at depths greater than six inches should not be averaged into the EPC. However, if the only data available is from a soil depth greater than the top 6 inches and contaminant levels at that depth exceed an Imminent Hazard Trigger Level, it should be assumed that the contaminant levels at depths greater than 6 inches are representative of the surficial soil.

In evaluating drinking water exposures, the MCP requires that the level of chemicals in the groundwater or surface water which serves as a source of drinking water must be considered in estimating the Exposure Point Concentration (310 CMR 40.0953(5)).

*For example, use of a filter cannot be considered in estimating the Exposure Point Concentration. Similarly, one cannot consider the potential dilution that may occur when a contaminated well or surface water body is not the exclusive source of drinking water.*

The EPC should represent the average concentration to which the receptor is exposed at the exposure point. However, there are some situations in which it is preferable to use a more conservative estimate of the EPC rather than a mid-range estimate that will be represented by an arithmetic average concentration. The MCP describes several specific situations in which the risk assessor should consider using an upper percentile or maximum concentration for the EPC, rather than an arithmetic average.

The situations listed in the MCP for which upper percentile or maximum concentrations may be appropriate for the EPC are as follows:

- evaluations of acute exposures;
- evaluations of chemicals with lethal or severe health effects;
- evaluations of sites for which there is insufficient site characterization data; or
- screening evaluations which are intended to over-estimate potential exposures.

As in a full risk assessment, a hot spot must be evaluated as a separate exposure point in an imminent hazard evaluation. This ensures that areas with high relative contamination will not simply be averaged into larger areas of lesser contamination, thereby diluting their potential impacts.

### **10.2.3. Dose Response**

The identification of a dose-response relationship(s) for each chemical being evaluated is done in the same manner as for a full risk assessment. The reader should consult Section 7.2 of the guidance document for a complete discussion of the information needed to describe the dose-response relationship. Toxicity information used to characterize risk in the imminent hazard evaluation must be appropriate for the type and duration of exposure being evaluated and must be clearly identified and documented in the imminent hazard evaluation report.

### **10.2.4 Risk Characterization**

The MCP contains numerical cancer and noncancer risk limits that are specific for imminent hazard evaluations (310 CMR 40.0955(2)). These risk limits represent a level of risk above which the Department has determined that a remedial action is needed in the short term.

Conditions at the site pose an Imminent Hazard if estimated cancer and noncancer risks for each OHM and for each receptor exceed the specified risk limits. The documentation of the Imminent Hazard evaluation must clearly state whether conditions at the site pose an Imminent Hazard (310 CMR 40.0955(4)).

#### 10.2.4.1 Cancer Effects

The MCP provides two risk management criteria for carcinogenic chemicals, depending on whether the risk assessment evaluates exposures over a "short period of time" or whether the risk assessment evaluates a long term exposure (typically 30 years or more). The risk assessor should select the risk limit that corresponds to the exposure period assessed in the imminent hazard evaluation.

*Recall that a "short" exposure period is the time period from the beginning of an exposure to five years or longer when exposures at the site have been ongoing for more than five years or if the final response action will not be implemented for more than five years.*

*Recall that long-term exposures (typically a 30-year exposure period) may be evaluated if the risk assessor so chooses.*

#### **Risk Management Criterion for exposures over a "short period of time"**

When the risk assessment evaluates cancer risks based on exposures over a "short period of time", conditions at a site pose an Imminent Hazard based on the potential for cancer health effects if:

- the estimated Excess Lifetime Cancer Risk is greater than an Excess Lifetime Cancer Risk Limit of one-in-one hundred thousand ( $1 \times 10^{-5}$ ).

#### **Risk Management Criterion for long-term exposures**

When the risk assessment evaluates cancer risks based on a long-term exposure period, conditions at a site pose an Imminent Hazard based on the potential for cancer health effects if:

- the estimated Excess Lifetime Cancer Risk is greater than an Excess Lifetime Cancer Risk Limit of one-in-ten thousand ( $1 \times 10^{-4}$ ).

#### **Rationale for Risk Management Criteria for Cancer Risks**

The limit for cancer risks which are estimated based on exposure over a "short period of time" is numerically identical to the cancer risk limit used to determine whether a site poses significant risk for purposes of achieving an RAO. However, recall that the cancer risk limit for final cleanup is based on long-term exposures. When a "short-term" exposure (i.e., an exposure occurring over less than five years, an exposure greater than five years that has occurred already, or an exposure greater than five years that will have

occurred by the time final remedial action is completed) results in an excess lifetime cancer risk (ELCR) higher than the risk limit of  $1 \times 10^{-5}$  for final cleanup, immediate remedial measures are warranted. The rationale is that further exposure, before or after long-term remediation is complete, could result in an ELCR above the risk limit.

The limit for cancer risks which are calculated based on a long-term exposure is less stringent (higher) than the risk limit for final cleanup because it represents a level of risk posed by a long-term exposure which the Department has determined must be addressed in the short term (i.e., such a high long-term risk is indicative of an unacceptable short-term risk).

#### **10.2.4.2 Non-Cancer Effects**

The MCP contains two risk management criteria based on the potential for noncarcinogenic health effects. The Department has developed two risk limits for noncancer effects because of the qualitative differences between toxicity values for different chemicals and how the toxicity values were derived.

##### **Risk Management Criteria for Non-Cancer Effects**

For chemicals for which the Uncertainty Factors and Modifying Factors incorporated in the Reference Dose are less than or equal to a factor of 10, conditions at a site pose an Imminent Hazard based on the potential for non-cancer effects if:

- the Hazard Index calculated for the site is greater than a Hazard Index equal to one.

For chemicals for which the Uncertainty Factors (UFs) and Modifying Factors (MFs) incorporated in the Reference Dose (RfD) are greater than a factor of 10, conditions at a site pose an Imminent Hazard based on the potential for non-cancer effects if:

- the Hazard Index calculated for the site is greater than a Hazard Index equal to ten.

*Note that the Reference Dose which is used must be appropriate for the type of exposure being evaluated. For example, if acute exposures are being evaluated, the risk assessor should use an acute Reference Dose.*

##### **Rationale for Risk Management Criteria for Non-cancer Risks**

When a Reference Dose is based on a robust and relatively complete toxicity database, there is reasonable certainty that the resulting Reference Dose is protective of adverse

health effects in sensitive humans. For these Reference Doses, EPA does not apply many UFs or MFs. Thus, when evaluating a chemical with a Reference Dose that has relatively few UFs and MFs (less than or equal to a factor of ten) the Hazard Index estimated for the site is compared with a Hazard Index limit of one.

Conversely, when the Reference Dose for a chemical is based on a less than ideal database, EPA incorporates multiple UFs and MFs to provide reasonable certainty that the resulting Reference Dose is protective of adverse health effects in sensitive humans. In other words, a RfD with many UFs and MFs indicates that there is greater uncertainty in how well the original toxicity data approximate a No Observed Adverse Effects Level. The multiple UFs and MFs are protective factors to compensate for the low level of confidence in the toxicity database used to develop the Reference Dose. A Reference Dose which has many UFs and MFs (greater than a factor of ten) has a large margin of safety already built into it. Thus, for these chemicals, the Hazard Index estimated for the site is compared with a less stringent Hazard Index limit of ten.

Due to large variations in the quality of toxicological data available, the US EPA incorporates Uncertainty Factors and Modifying Factors into the Reference Dose to reflect the quality of the data and to insure that the Reference Dose falls below a No Observed Adverse Effects Level in sensitive humans. Uncertainty and Modifying Factors are typically applied to account for interspecies variation, conversion of a Lowest Observed Adverse Effects Level (LOAEL) to a No Observed Adverse Effects Level (NOAEL), exposure duration and protection of sensitive human populations. The less confidence there is in the original toxicity data, the larger the UFs and MFs. It is not uncommon that a Reference Dose incorporates combined factors as large as 10,000.

On the other hand, the toxicological information available for some chemicals is complete, and the Uncertainty and Modifying Factors used to adjust the Reference Dose are quite small: sometimes less than a factor of ten.

Uncertainty Factors and Modifying Factors are part of the documentation that accompanies a Reference Dose published by EPA on IRIS or HEAST. A discussion of UFs and MFs can be found in the Dose-Response Section (Section 7.2.1).

It is important to recognize that where noncancer risks dominate over cancer risks, it is DEP's objective to make imminent hazard risk management decisions based on a Lowest Observable Adverse Effects Level, rather than a No Observable Adverse Effects Level. In other words, it is DEP's intent to make decisions about the need for immediate action based on a chemical dose that is associated with an adverse health effect and not a dose that is associated with no adverse effect (i.e. a "safe" dose). One of the factors DEP considered in developing the non-cancer risk management criteria for imminent hazards is the fact that Reference Doses for many chemicals include an UF of 10 to convert a

Lowest Observable Adverse Effects Level (LOAEL) to a No Observed Adverse Effects Level (NOAEL). Using a HI limit of 10 offsets the 10-fold UF for the LOAEL to NOAEL conversion. In this way, DEP's imminent hazard risk management decisions are more closely based on the Lowest Observable Adverse Effects Level. This is meant to be a generalized approach, as DEP recognizes that toxicity values for some chemicals (which have UFs greater than 10) do not incorporate the LOAEL to NOAEL adjustment.

### 10.3 IMMINENT HAZARD EVALUATIONS FOR THE ENVIRONMENT

As previously stated, the MCP does not define specific conditions at a site which trigger an imminent hazard evaluation. Rather, the application of professional judgement is relied upon to determine when site conditions warrant an Imminent Hazard Evaluation for environmental receptors.

The MCP provides the following two criteria for determining whether conditions at the site pose an Imminent Hazard to the environment (310 CMR 40.0955(3)).

- conditions pose an Imminent Hazard if there is visible evidence of stressed biota attributable to the disposal site.
- conditions at the disposal site pose an Imminent Hazard if the Risk Characterization demonstrates that significant adverse ecological impacts are likely under current site conditions and that those impacts are likely to persist if the current conditions were to remain for up to five years.

What is intended in the first criterion is that there must be readily apparent evidence of severe impacts on ecological receptors in order for the site to pose an Imminent Hazard to the environment. The risk assessor should focus on identifying whether there are visible signs that ecological receptors are being severely impacted. It is not intended that a Stage I Screening, as described in Section 9.0, will be needed to accomplish this. Rather the risk assessor should rely on visual observations and professional judgement. Evidence of an impact such as a fish kill clearly should be considered visible evidence of stressed biota.

In the second criterion, conditions at the disposal site must be such that severe or life threatening impacts on ecological receptors are likely. Again, it is not intended that a detailed evaluation will be needed to identify whether such conditions exist at the site. The risk assessor should use simple measures, along with professional judgement to determine whether environmental receptors are seriously threatened. Evidence of abiotic conditions at the site could potentially be a condition that is likely to pose a severe impact on ecological receptors.

In general, quantitative risk assessment procedures do not provide a distinction between an environmental Imminent Hazard and environmental long-term risk. Thus, the MCP provides no numerical criteria for an environmental Imminent Hazard and DEP does not intend quantitative risk assessment procedures to be used in determining whether conditions at a site pose an Imminent Hazard to the Environment.

*Recall that Subpart C of the MCP (310 CMR 40.0321(1)(e)) describes the following release which requires notification to DEP within 2 hours because it poses an Imminent Hazard to the environment:*

- *a release to the environment that produces immediate or acute adverse impacts to freshwater or saltwater fish populations.*

#### **10.4 IMMINENT HAZARD EVALUATIONS FOR SAFETY**

The MCP provides that conditions at the site pose an Imminent Hazard to Safety if there is a significant risk to safety under existing conditions or conditions which are about to occur. As defined in the MCP, a significant risk to safety exists at a site if a release poses a threat of physical harm or bodily injury to people.

In accordance with the MCP, an Imminent Hazard evaluation for safety concerns must be conducted following the provisions detailed in 310 CMR 40.0960. Guidance relating to characterizing the risk of harm to safety is provided in Section 4.0. However, an imminent hazard for Safety will be more narrow in scope than the evaluation described in 310 CMR 40.0960. In identifying whether an Imminent Hazard to Safety exists, the risk assessor need only focus on existing conditions (or conditions which are about to occur), and the receptors actually present given the current use of the site. Examples of a potential Imminent Hazard to Safety include: (1) exceeding an explosive limit within a structure; and (2) the presence of insecurely containerized waste.

#### **10.5 IMMINENT HAZARD EVALUATIONS TO PUBLIC WELFARE**

In general, a condition at a site that precludes the full use of a resource should be evaluated as a potential Imminent Hazard to Public Welfare. For example, a condition such as an odor in a residence that prevents people from living there, or taste or odors problems in drinking water that preclude using it for consumptive purposes certainly should be considered as a potential Imminent Hazard to Public Welfare. The Department expects that in general, Imminent Hazards to public welfare will be rare.

## **APPENDIX A**

## **GLOSSARY OF TERMS & ACRONYMS**

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SUBJECT: [illegible]

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## APPENDIX A: GLOSSARY OF TERMS AND ACRONYMS

AAL means Allowable Ambient Level in air, in units of  $\mu\text{m}^3$ , (from *The Chemical Health Effects Methodology and The Method to Derive Allowable Ambient Limits*, MADEP/ORS Publication 90-1, May 1990).

ACEC means an Area of Critical Environmental Concern.

ADD means Average Daily Dose of a contaminant received by a receptor of concern.

ADE means Average Daily Exposure.

ADSCR means Average Daily Soil Contact Rate ( $\text{mg}_{\text{soil}}/\text{kg}/\text{day}$ ).

ADSIR means Average Daily Soil Intake Rate ( $\text{mg}_{\text{soil}}/\text{kg}/\text{day}$ ).

AF means Fraction of OHM in soil Absorbed through the skin (unitless).

AP means Averaging Period (units: days).

Aquifer means a geologic formation, group of formations or part of a formation that is capable of yielding a significant amount of groundwater to wells or springs.

Area of Critical Environmental Concern and ACEC each means an area which has been so designated by the Secretary of Environmental Affairs pursuant to 301 CMR 12.00.

Assessment Endpoint means a specific effect on a specific group of organisms that is evaluated in a quantitative environmental risk characterization.

ATC means Allowable Threshold Concentration (in air).

AUL means Activity and Use Limitation.

AWQC means Ambient Water Quality Criteria.

Background means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern which meet the regulatory definition in the MCP which is:

- (a) ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern; and
- (b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, releases to groundwater from a public water supply system and/or petroleum residues that are incidental to the normal operation of motor vehicles.

Biota means plant or animal life.

BRP means the Massachusetts DEP Bureau of Resource Protection.

BW means Body Weight of the receptor of concern during the period of exposure (units: mass).

BWP means the Massachusetts DEP Bureau of Waste Prevention.

BWSC means the Massachusetts DEP Bureau of Waste Site Cleanup.

C means appropriate units Conversion factor.

c.21E means Massachusetts Law Chapter 21E, The Massachusetts Oil and Hazardous Material Release Prevention and Response Act.

CAG means the U.S. EPA's Carcinogen Assessment Group.

CAS means Chemical Abstract Service.

Carcinogenic Slope Factor means the cancer risk (proportion affected) per unit dose of an oil or hazardous material, as published by EPA.

CERCLA means (U.S.) Comprehensive Environmental Response and Liability Act of 1980.

Class A Surface Water Body means any segment of an inland or coastal surface water body so assigned "Class A" pursuant to 314 CMR 4.00.

CMR means Code of Massachusetts Regulations.

Coastal waters means the Atlantic Ocean and all contiguous saline bays, inlets and harbors within the jurisdiction of the Commonwealth including areas where fresh and salt waters mix and tidal effects are evident or any partially enclosed coastal body of water where the tide meets the current of a stream or river.

Cumulative Receptor Cancer Risk means the sum of the estimated excess lifetime cancer risks associated with exposure to all oil and/or hazardous material at or from a disposal site at all exposure points for a given receptor.

Cumulative Receptor Non-cancer Risk means a calculation of the possibility of non-cancer health effects associated with exposure to all oil and/or hazardous material at or from a disposal site at all exposure points identified for a given receptor. The Hazard Index is a measure of the Cumulative Receptor Non-cancer Risk.

DAQC means the Massachusetts DEP Division of Air Quality Control.

DDD means 2,2-bis(p-chlorophenyl)-1,1-dichloroethane.

DDE means dichlorodiphenyldichloroethylene.

DDT means 1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane.

Department and DEP each means the Massachusetts Department of Environmental Protection.

DEQE means the Massachusetts Department of Environmental Quality Engineering, which is the former name of the Massachusetts Department of Environmental Protection.

Disposal site means any structure, well, pit, pond, lagoon, impoundment, ditch, landfill or other place or area, excluding ambient air or surface water, where uncontrolled oil and/or hazardous material has come to be located as a result of any spilling, leaking, pouring, abandoning, emitting, emptying, discharging, injecting, escaping, leaching, dumping, discarding or otherwise disposing of such oil and/or hazardous material. The term shall not include any site containing only oil or hazardous materials which: are lead-based paint residues emanating from a point of original application of such paint; resulted from emissions from the exhaust of an engine; are building materials still serving their original intended use or emanating from such use; or resulted from release of source, byproduct or special nuclear material from a nuclear incident, as those terms are defined in 42 U.S.C. § 2014, if such release was subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under 42 U.S.C. § 2210.

DNAPL means Dense Non-Aqueous Phase Liquid.

Dose means the amount of a substance, expressed in mg/kg body weight/day, which is absorbed into the body as a result of exposure(s).

DWPC means the Massachusetts DEP Division of Water Pollution Control.

DWS means the Massachusetts DEP Division of Water Supply.

ED means the average Duration of each Exposure Event (units: hours/event).

EF means the average number of Events/day during the period of exposure (units: events/day).

ELCR means Excess Lifetime Cancer Risk.

Endangered species means those vertebrate and invertebrate animal species officially listed as endangered by the Massachusetts Division of Fisheries and Wildlife under 321 CMR 10.00.

Environment means waters, land, surface or subsurface strata, or ambient air of the Commonwealth.

Environmental Receptor means any living organism, other than humans, and/or any habitat which supports such organisms, and/or any other natural resource which comes into contact with oil and/or hazardous material as a result of a release to the environment.

Environmental Restriction means a restriction or other covenant concerning the use of property that is held or imposed by the Department pursuant to M.G.L. c. 21E, § 6.

EP means the duration of the Exposure Period (units: days).

EPA means the U.S. Environmental Protection Agency.

EPC means Exposure Point Concentration.

Excess Lifetime Cancer Risk means the estimated probability that an individual's exposure during a lifetime to an oil or hazardous material could result in cancer.

Exposure means any contact with or ingestion, inhalation or assimilation of oil and/or hazardous material, including, without limitation, irradiation.

Exposure Pathway means the mechanism by which human or environmental receptors inhale, consume, absorb, or otherwise take in oil and/or hazardous material at an Exposure Point.

Exposure Point means a location of potential contact between a human or environmental receptor and a release of oil and/or hazardous material. An Exposure Point may describe an area or zone of potential exposure, as well as a single discrete point.

Exposure Point Concentration means the concentration of oil or hazardous material in a specific medium which a human or environmental receptor may contact at an Exposure Point.

FI means the daily Intake of contaminated Food on days exposed during the exposure period (units: mass/event).

Fish habitat means any surface water body that serves as a habitat for fresh or marine fauna, including, but not limited to, crustacean, fin fish and shellfish. For purposes of the Numerical Ranking System, the entire coastline of Massachusetts is considered a fish habitat.

Groundwater means any water below the earth's surface in the zone of saturation.

GW-1 means groundwater category for current or potential drinking water source.

GW-2 means groundwater category for a source of volatiles to indoor air.

GW-3 means groundwater category everywhere in the commonwealth of Massachusetts.

Habitat means the area or type of environment in which an organism or biological population normally lives or occurs, including, without limitation, wetland habitat, woodland habitat, grassland habitat and mountain habitat.

Hazard Index means a calculation of the possibility of non-cancer health effects as the result of exposure to one or more oil or hazardous materials with the same or similar modes of toxic action or toxic endpoints. The Hazard Index (HI) is defined as:  $HI = D1/AD1 + D2/AD2 + \dots + Di/ADi$  where D is the daily dose (or daily concentration) for a particular oil or hazardous material, and AD is the allowable daily dose (or allowable daily concentration) for a particular oil or hazardous material specified by the Department. The allowable daily concentration is the Reference Concentration or other allowable daily concentration specified by the Department.

Hazardous material means material, including, but not limited to, any material in whatever form which, because of its quantity, concentration, chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with any substance or substances, constitutes a present or potential threat to human health, safety, welfare, or to the environment, when improperly stored, treated, transported, disposed of, used, or otherwise managed. The term shall not include oil, but shall include waste oil and all those substances which are included under 42 U.S.C. § 9601(14), but it is not limited to those substances. The term shall also include, but is not limited to, material regulated as hazardous waste or recyclable material under 310 CMR 30.000.

HEAST means the U.S. EPA's Health Effects Assessment Summary Tables.

HI means Hazard Index.

Hot Spot means a discrete area where the concentrations of oil or hazardous material are substantially higher than those concentrations in the surrounding area as defined in the MCP.

Human Receptor means a person who is likely to be affected by a site, as further described in 310 CMR 40.0900.

IARC means the International Agency for Research on Cancer.

IH means Imminent Hazard.

Immediate Response Action and IRA each means any response action performed in accordance with 310 CMR 40.0410.

Imminent Hazard means a hazard which would pose a significant risk of harm to health, safety, public welfare or the environment if it were present for even a short period of time, as further described in 310 CMR 40.0950.

Imminent Hazard Evaluation means an evaluation performed in accordance with 310 CMR 40.0951 through 310 CMR 40.0955.

Interim Wellhead Protection Area or IWPA means:

- (a) with respect to public water supply wells and wellfields whose pumping rate is 100,000 gallons per day or greater and for which the Department has not approved a hydrologically delineated Zone II, the ½ mile radius surrounding such well or wellfield; and
- (b) with respect to public water supply wells and wellfields whose pumping rate is less than 100,000 gallons per day and for which the Department has not approved a hydrologically delineated Zone II, the radius calculated by multiplying the maximum pumping rate in gallons per minute for such well or wellfield by 32 and adding 400 feet thereto (i.e.  $IWPA = 32y + 400$ ; where  $y$  = pumping rate in gallons per minute).

IR means the daily soil Ingestion Rate on days exposed during the exposure period (units: mass/day).

IRA means Immediate Response Action.

IRIS means the US EPA's Integrated Risk Information System.

LADD means Lifetime Average Daily Dose.

LADSCR means Lifetime Average Daily Soil Contact Rate normalized to bodyweight ( $\text{mg}_{\text{soil}}/\text{kg}/\text{day}$ ).

LADSIR means Lifetime Average Daily Soil Intake Rate normalized to bodyweight ( $\text{mg}_{\text{soil}}/\text{kg}/\text{day}$ ).

Lake means any open body of fresh water with a surface area of ten acres or more, including, without limitation, Great Ponds.

Leaching means the percolation or draining of liquid through oil and/or hazardous material.

LEL means Lower Explosive Limit.

Licensed Site Professional and LSP each means a hazardous waste site cleanup professional, as defined in M.G.L. c. 21A, § 19, holding a valid license issued by the Board of Registration of Hazardous Waste Site Cleanup Professionals pursuant to M.G.L. c. 21A, §§ 19 through 19J.

MA DEP means the Massachusetts Department of Environmental Protection.

Massachusetts Contingency Plan and MCP and this Contingency Plan each means 310 CMR 40.0000.

MCL means Maximum Contaminant Level.

MMCL means Massachusetts Maximum Contaminant Level.

MDL means Method Detection Limit.

Measurement Endpoint means the result of a measurement that is used to evaluate an assessment endpoint.

Media means air, soil, water or sediment, etc.

Method Detection Limit means, generally, the level which can be measured with 99% accuracy using EPA Standard Methods.

MGL means Massachusetts General Law.

Migration pathway means a pathway by which oil and/or hazardous material is transported at or from a disposal site.

Multi-media means the most common contamination scenario. A disposal site where exposure is thought to occur via more than one exposure medium.

Modifying Factor (MF) means a factor greater than zero and less than or equal to 10 by which a no-observed-adverse-effect level is divided to estimate a Reference Dose. The MF reflects qualitative professional judgments regarding scientific uncertainties not covered under the standard Uncertainty Factors, such as the completeness of the overall data base and the number of animals in the experimental study.

MOHML means the Massachusetts Oil and Hazardous Material List.

Monitoring well means a well designed to facilitate the down-hole measurement of groundwater and/or gas levels and the collection of groundwater and/or gas samples.

MW means Molecular Weight.

NAPL means Non-Aqueous Phase Liquid.

ND means Not Detected.

NFA means No Further Action.

No Significant Risk means a level of control of each identified substance of concern at a site or in the surrounding environment such that no such substance of concern shall present a significant risk of harm to health, safety, public welfare or the environment during any foreseeable period of time.

NOAEL means the No Observable Adverse Effects Level.

Nonaqueous Phase Liquid and NAPL each means oil and/or hazardous material that is present in the environment as a continuous separate phase as measured in a groundwater monitoring well or otherwise observed in the environment.

NSR means No Significant Risk.

OHM means Oil and/or Hazardous Material.

Oil means insoluble or partially soluble oils of any kind or origin or in any form, including, without limitation, crude or fuel oils, lube oil or sludge, asphalt, insoluble or partially insoluble derivatives of mineral, animal or vegetable oils and white oil. The term shall not include waste oil, and shall not include those substances which are included in 42 U.S.C. § 9601(14).

Outstanding Resource Waters means waters in the Commonwealth given a protected status due to their ecological, socioeconomic, recreational, and/or aesthetic value pursuant to 314 CMR 4.04(3).

PCBs means Polychlorinated Biphenyls.

Permanent Solution means a measure or combination of measures which will, when implemented, ensure attainment of a level of control of each identified substance of concern at a disposal site or in the surrounding environment such that no substance of concern will present a significant risk of damage to health, safety, public welfare, or the environment during any foreseeable period of time.

Playground (see Park, playground and recreation area).

Point source means a discernible, confined and discrete conveyance, including, but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock or vessel from which oil and/or hazardous material is or may be discharged.

Pond means any coastal or inland pond, as defined in 310 CMR 10.04.

Potentially productive aquifer means:

- (a) all aquifers delineated by the U.S. Geological Survey (USGS) as a high or medium yield aquifer, except for any portion of a high or medium yield aquifer that is located in a municipality with a population density equal to or greater than 4,400 persons per square mile (based on the most recent U.S. Census); and
- (b) all aquifers located east of the Cape Cod Canal (Cape Cod), on the Elizabeth Islands, on Martha's Vineyard, or on Nantucket.

*NOTE (7/95): The definition of Potentially Productive Aquifer and the rules for classification of PPAs as GW-1 aquifers are under review. Please consult the latest version of the MCP for the current definition.*

Potentially Responsible Party and PRP each means a person who is potentially liable pursuant to M.G.L. c. 21E.

PPA means Potentially Productive Aquifer.

ppb means parts per billion.

ppm means parts per million.

PQL means Practical Quantitation Limit.

Practical Quantitation Limit means, generally, the smallest concentration of a substance for which quantitative results may be obtained with a specified degree of confidence.

Private water supply well means a well which is utilized by a private water system. For purposes of 310 CMR 40.0000, the phrase "private water system" is used to refer to a system for the provision of piped water for human consumption which has fewer than 15 service connections or does not regularly serve an average of at least 25 individuals daily at least 60 days of the year.

Protected Open Space means

- (a) any federal, state or local government-protected open space, including, but not limited to, parks, forests and watershed lands;
- (b) any land used for conservation purposes by a non-profit corporation, such as the Massachusetts Audubon Society, the Trustees of Reservation (excluding land held for its historic value only) and the Nature Conservancy; and
- (c) excluding any privately held land associated with a conservation restriction or easement or controlled by a person other than a non-profit corporation or Agency.

PRP means Potentially Responsible Party.

Public water supply means a source of water supply, including, but not limited to, primary, backup and emergency sources, utilized by a public water system. For purposes of 310 CMR 40.0000, the terms "public water system," "primary source," "backup source," and "emergency source" shall have the meaning ascribed to such terms by 310 CMR 22.02.

Public water supply distribution pipeline means any piping used for the conveyance of potable water in a public water system.

Public Way means land in use as a public street or highway.

$q_1^*$  means the US EPA's Cancer Assessment Group's published cancer slope value.

RAF means Relative Absorption Factor (unitless).

Rail Right-of-Way means lands or interests in lands which are in use as rights-of-way for rail purposes. This definition includes rights-of-way which are in use for rail transportation as regulated by M.G.L. c. 161C, and rail rights-of-way which are in use by the Massachusetts Bay Transportation Authority. This definition does not include related facilities, such as rail yards and rail maintenance facilities.

RAO means Response Action Outcome:

- Class A: Permanent Solution Achieved
- Class B: No Remedial Action Required
- Class C: Temporary Solution

RAPS means Response Action Performance Standard.

RC means Reportable Concentration.

RCGW-1 means Reportable Concentration for Groundwater in Category 1 (groundwater resource areas).

RCGW-2 means Reportable Concentration for Groundwater in Category 2 (groundwater everywhere else).

RCRA means the Federal Solid Waste Disposal Act as revised by the Resource Conservation and Recovery Act of 1976, P.L. 94-580, 42 U.S.C. §§ 6901 *et seq.*, as amended.

RCS-1 means Reportable Concentration for Soil in Category 1 (higher exposure potential).

RCS-2 means Reportable Concentration for Soil in Category 2 (soil everywhere else).

Receptor means a Human Receptor or Environmental Receptor. Which is an individual or environmental population exposed to oil or hazardous materials.

Recreation area (See Park, playground and recreation area).

Reference Concentration means the daily concentration in air of an oil and/or hazardous material which would not be expected to result in any adverse non-cancer health effects, as published by EPA.

Reference Dose means the daily dose of an oil or hazardous material which would not be expected to result in any adverse non-cancer health effects, as published by EPA.

Relative Absorption Factor means a factor which adjusts the dose estimate in consideration of the absorption efficiencies of the study which is the basis of the toxicity information and the absorption efficiency of the route of exposure of concern. It is not itself an absorption efficiency. This term was formerly called a "Bioavailability Adjustment Factor" by the Department.

Release means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping or disposing into the environment, but excludes:

- (a) emissions from the exhaust of an engine;
- (b) release of source, byproduct, or special nuclear material from a nuclear incident, as those terms are defined in 42 U.S.C. § 2014, if such release is subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under 42 U.S.C. § 2210;
- (c) the normal application of fertilizer;
- (d) the application of pesticides in a manner consistent with their labelling; and
- (e) the application of residuals in accordance with 310 CMR 32.00.

Remedial action means any containment or removal.

Remedial alternative means a measure or combination of measures identified and evaluated in accordance with 310 CMR 40.0850 for its effectiveness in reducing, mitigating or eliminating risks posed by a disposal site.

Reportable Concentration and RC each means the concentration of oil or hazardous material in soil or groundwater which requires notification to the Department under M.G.L. c. 21E, § 7, and/or 310 CMR 40.0360 through 310 CMR 40.0362.

Reportable Quantity and RQ each means the quantity of oil or hazardous material the release of which, or threat of release of which, requires notification to the Department under M.G.L. c. 21E, § 7, and/or 310 CMR 40.0350 through 310 CMR 40.0352.

Residual contamination means the concentrations of oil and/or hazardous material remaining at a site at which further remedial actions are not required by these regulations.

Respond, response and response action each means assess, assessment, contain, containment, remove or removal.

Response Action Outcome and RAO each means the classification applied to a disposal site at which there is No Significant Risk, as further defined by 310 CMR 40.1000.

Response Action Outcome Statement means an LSP Opinion submitted to the Department in accordance with 310 CMR 40.1000.

Response Action Performance Standard and RAPS each means the level of diligence reasonably necessary to obtain the quantity and quality of information adequate to assess a site, to evaluate remedial action alternatives and to design and implement appropriate remedial actions, as further defined by 310 CMR 40.0191.

RfC means the U.S. EPA's published Reference Concentration.

RfD means the U.S. EPA's published Reference Dose.

Risk Characterization means the requirements and procedures for characterizing risks of harm to health, safety, public welfare and the environment set forth in 310 CMR 40.0900.

River means a waterbody contained within a channel, naturally or artificially created, which periodically or continuously contains flowing water or forms a connecting link between two bodies of standing water.

Route of exposure means a mechanism by which an oil or hazardous material comes into contact with a receptor, including, but not limited to, ingestion, inhalation, dermal absorption and transpiration.

RP means Respirable Particulates (units: mass).

S-1 means Soil category with high exposure potential.

S-2 means Soil category with medium exposure potential.

S-3 means Soil category with low exposure potential.

SA means Skin Surface Area in contact with the contaminated soil on days exposed (units: area/day).

School means any public or private elementary or secondary school, and any day care center, as defined in M.G.L. c. 28A, § 9.

Sediments means all detrital and inorganic or organic matter situated on the bottom of lakes, ponds, streams, rivers, the ocean, or other surface water bodies. Sediments are found:

- (a) in tidal waters below the mean high water line as defined in 310 CMR 10.23; and
- (b) below the upper boundary of a bank, as defined in 310 CMR 10.54(2), which abuts and confines a water body.

Sheen means an iridescent appearance of any oil or waste oil on the surface of any river, stream, lake, pond, spring, impoundment, estuary, coastal water or groundwater. The term "sheen" shall not include detrital, inorganic or organic matter located in a terrestrial environment.

ShortForm means the Risk Assessment ShortForm, the spreadsheet risk assessment tool.

Site means any building, structure, installation, equipment, pipe or pipeline, including any pipe discharging into a sewer or publicly-owned treatment works, well, pit, pond, lagoon, impoundment, ditch, landfill, storage container, motor vehicle, rolling stock, or aircraft, or any other place or area where oil or hazardous material has been deposited, stored, disposed of or placed, or otherwise come to be located. The term shall not include any consumer product in consumer use or any vessel.

Site Activities and Uses means the uses and activities associated with a disposal site and the surrounding environment, as further defined by 310 CMR 40.0923.

Soil means any unconsolidated mineral and organic matter overlying bedrock that has been subjected to and influenced by geologic and other environmental factors, excluding sediment.

Sole Source Aquifer means an aquifer designated by EPA as the sole or principal source of drinking water for an area pursuant to § 1424(e) of the federal Safe Drinking Water Act, as amended.

Species of Special Concern means those vertebrate and invertebrate animal species officially listed as species of special concern by the Massachusetts Division of Fisheries and Wildlife under 321 CMR 10.00.

SRM means Substantial Release Migration, as further described in 310 CMR 40.0413.

Stream means a body of running water, including brooks and creeks, which moves in a definite channel in the ground due to a hydraulic gradient, and which flows within, into or out of an "Area Subject to Protection Under the Act," as defined in 310 CMR 10.04.

Substantial hazard means a hazard which would pose a significant risk of harm to health, safety, public welfare, or the environment if it continued to be present for several years.

Surface water means all waters other than groundwater within the jurisdiction of the Commonwealth, including, without limitation, rivers, streams, lakes, ponds, springs, impoundments, estuaries, wetlands, coastal waters and vernal pools.

SVOC means Semi-Volatile Organic Compound.

TEL means Threshold Effects Level in air, in units of  $\mu\text{g}/\text{m}^3$ , (from *The Chemical Health Effects Methodology and The Method to Derive Allowable Ambient Limits* MADEP/ORS publication 90-1, May 1990).

Temporary Solution means any measure or combination of measures which will, when implemented, eliminate any substantial hazard which is presented by a disposal site or by any oil and/or hazardous material at or from such site in the environment until a Permanent Solution is achieved.

Threatened Species means those vertebrate and invertebrate animal species officially listed as threatened species by the Massachusetts Division of Fisheries and Wildlife under 321 CMR 10.00.

Threat of release means a substantial likelihood of a release of oil and/or hazardous material which requires action to prevent or mitigate damage to health, safety, public welfare or the environment which may result from the release. Circumstances which represent a threat of release include, but are not limited to, sites containing or conducting an amount of oil and/or hazardous material in excess of the Reportable Quantity for that oil and/or hazardous material, or of an unknown quantity, where no release has occurred but where a person required by 310 CMR 40.0331 to report the threat of release has knowledge of any corrosion, damage, malfunction or other condition that is likely to result in a release.

TOR means Threat of Release.

Total Petroleum Hydrocarbons and TPH each means the total or cumulative concentration of hydrocarbons associated with a petroleum product with a gram molecular weight equal to or greater than 140 ( $\text{C}_{10}$ ), as measured by standard analytical techniques and/or by procedures approved by the Department, including, but not limited to, procedures approved by the Department that express TPH as a weighted average of individual constituents.

UCL means Upper Concentration Limit.

UF means Uncertainty Factor.

Uncertainty Factor means one or more factors, each generally an order of magnitude, by which a no-observed-adverse-effect level is divided in accordance with EPA-approved methodology to reflect uncertainty in the various types of data used to estimate a Reference Dose.

Unit Risk means the cancer risk (proportion affected) per concentration unit of an oil or hazardous material, as published by EPA.

Upgradient means

- (a) in reference to surface water, the direction perpendicular to lines of equal elevation over a distance in which elevation continuously increases, measured from the point or area in question; or
- (b) in reference to groundwater, the direction perpendicular to lines of equipotential over a distance in which total head continuously increases, measured from the point or area in question.

UR means Unit Risk value.

Vadose zone means the unsaturated zone below the ground surface and above the water table.

Vernal pool means a water body that has been certified by the Massachusetts Division of Fisheries & Wildlife as a vernal pool.

Vernal pool habitat means any confined basin depression which, at least in most years, holds water for a minimum of two continuous months during the spring and/or summer, and which are free of adult fish populations, as well as the area within 100 feet of the mean annual boundaries of the depressions, to the extent that the habitat is within an Area Subject to Protection Under the Wetlands Protection Act, as specified in 310 CMR 10.02(1).

VI means the daily Volume of drinking water Ingested by the receptor of concern at the exposure point during the exposure period (units: volume/day).

Volatilization means the conversion of all or part of a liquid or solid into vapor.

Volatile Organic Compounds and VOCs each mean an organic compound with a boiling point less than 200 degrees Celsius that are targeted analytes in EPA Method 8240 and other purgeable organic methods specified in EPA publication SW-846 entitled, "Test Methods for Evaluating Solid Waste."

VR means the daily Respiratory Volume for the receptor of concern during the period of exposure (units: volume/day).

Water Quality Criteria and Ambient Water Quality Criteria each means the concentrations of oil and/or hazardous material in water developed by EPA pursuant to § 304(a)(1) of the federal Water Pollution Control Act, as amended.

Water Quality Standards means the Massachusetts Surface Water Quality Standards (314 CMR 4.00) and the Massachusetts Groundwater Quality Standards (314 CMR 6.00).

Water table means the upper elevation of the surface of the saturated zone.

Well means a bored, drilled or driven shaft, or a dig hole, whose depth is greater than its largest surface dimension.

Wetland means any area subject to protection under the Wetlands Protection Act, M.G.L. c. 131, § 40, the regulations published at 314 CMR 9.00 under the Massachusetts Clean Waters Act, or Section 401 of the federal Water Pollution Control Act, 33 U.S.C. 1341, as amended.

Wildlife means any mammal, bird, reptile, amphibian, fish, or other vertebrate or invertebrate animal species.

[ X ]<sub>y</sub> means the concentration of substance "X" in medium "y".

Zone A means the area within 400 feet laterally from the bank of a Class A surface drinking water source (as identified in 314 CMR 4.00) and its tributaries.

Zone B means an area either ½ mile from the bank of a Class A surface drinking water source, or the watershed boundary, whichever is less.

Zone I means the area within the protective radius surrounding a public water supply well or wellfield required by 310 CMR 22.00.

Zone II means that area of an aquifer which contributes water to a well under the most severe pumping and recharge conditions that can be realistically anticipated, as approved by the Department's Division of Water Supply pursuant to 310 CMR 22.00.

Zone III means that land area beyond the area of Zone II from which surface water and groundwater drain into Zone II. The surface drainage area, as determined by topography, is commonly coincident with the groundwater drainage area and is used to delineate Zone III. In some locations, where surface and groundwater drainage are not coincident, Zone III shall consist of both the surface drainage and the groundwater drainage areas.

Zone of saturation means any part of the earth's crust in which all voids are filled with water.

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SUBJECT: [Subject]

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## **APPENDIX B**

### **SUGGESTED DEFAULT EXPOSURE ASSUMPTIONS**



## APPENDIX B: SUGGESTED DEFAULT EXPOSURE ASSUMPTIONS

This Appendix contains default exposure assumptions which may be used in the exposure assessment to calculate dose. In the absence of site specific, or otherwise justifiable exposure information, the use of DEP's default values will result in realistic yet adequately conservative dose estimates. The selection of all exposure assumptions should be described in narrative form, accompanied by a referenced summary table.

It is important to differentiate between site-specific information which can be appropriately used to modify site-specific parameters and professional judgement about the scientific evidence which supports generic assumptions. DEP does not support the modification of default exposure assumptions in a site-specific risk assessment solely on the basis of a differing interpretation of the supporting science. Rather, only those default exposure assumptions for which there is a reasonable basis for site-specific differences, should be modified. In DEP's view, some exposure assumptions in this Appendix should not be modified (in the absence of additional studies not previously considered in establishing the default values) because there is no reason to expect that the exposure assumption would differ from site to site. For example, DEP does not support "*site-specific*" modification of the default soil ingestion rate because there is no reason to expect the rate of soil ingestion to differ from site to site.

References have been provided for default values and for background information. Consult the index on the following page for easy reference to a particular exposure parameter.

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## A. Body Weights

Table B-1 provides age-specific body weights for children and adults. The body weights are 50th percentile values for males and females and are presented annually for children and at longer intervals for adults. For children less than 3 years old, body weights were taken from a pediatric growth chart. For all others, values were obtained from the U.S. Environmental Protection Agency (EPA) Exposure Factors Handbook.

### Sources:

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

US EPA, Exposure Factors Handbook -- Final Report, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA/600/8-89-0430] (March 1989).

Massachusetts General Hospital, *Pediatric Growth Charts*, Department of Pediatrics, Boston, MA (1976).

## B. Skin Surface Area

Table B-2 provides age-specific body surface areas for adults and children. Surface areas for body parts are the 50th percentile values. Values are presented annually for children and at longer age intervals for adults. For children less than 3 years old, surface areas were calculated from weights and body lengths obtained from a pediatric growth chart. For all other ages, surface areas for body parts were taken from EPA's Exposure Factors Handbook. For body parts not provided in EPA's Exposure Factors Handbook, surface areas were calculated by multiplying the total surface area by the proportion assigned to that body part by EPA.

### Sources:

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

US EPA, Exposure Factors Handbook -- Final Report, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA/600/8-89-0430] (March 1989).

Massachusetts General Hospital, *Pediatric Growth Charts*, Department of Pediatrics, Boston, MA (1976).

TABLE B-1

## AGE-SPECIFIC BODY WEIGHTS FOR CHILDREN AND ADULTS

AGE (Years)	50th Percentile Body Weight for Females (Kg)	50th Percentile Body Weight for Males (Kg)
<1	8.5	9.2
1<2	10.8	11.5
2<3	12.6	13.4
3<4	14.6	15.3
4<5	16.4	17.4
5<6	18.8	19.3
6<7	21.0	21.9
7<8	23.5	24.4
8<9	27.3	27.3
9<10	29.6	29.7
10<11	34.3	34.5
11<12	40.0	36.4
12<13	45.2	42.1
13<14	48.6	47.7
14<15	52.8	55.5
15<16	53.9	60.2
16<17	55.3	63.6
17<18	58.3	65.7
18<25	57.1	70.9
25<35	59.9	76.7
35<45	62.4	78.9
45<55	64.4	78.1
55<65	64.4	76.8
65<75	63.8	73.2

**TABLE B-2. Age-Specific Skin Surface Area**

MEDIAN (50th Percentile) AGE-SPECIFIC SKIN SURFACE AREA (cm <sup>2</sup> )									
PART OF THE BODY	<1	1<2	2<3	3<4	4<5	5<6	6<7	7<8	8<9
TOTAL BODY SURFACE, MALE	4031	5303	6030	6640	7410	7930	8660	9360	10000
TOTAL BODY SURFACE, FEMALE	3820	5183	5790	6490	7060	7790	8430	9170	10000
HEAD, MALE	733.6	875.0	856.3	903.0	1022.6	1094.3	1134.5	1226.2	1310.0
HEAD, FEMALE	695.2	855.2	822.2	882.6	974.3	1075.0	1104.3	1201.3	1310.0
TRUNK, MALE	1439.1	1882.6	2321.6	2118.2	2334.2	2498.0	3039.7	3285.4	3510.0
TRUNK, FEMALE	1363.7	1840.0	2229.2	2070.3	2223.9	2453.9	2958.9	3218.7	3510.0
ARMS, MALE	475.7	625.8	711.5	956.2	1037.4	1110.2	1134.5	1226.2	1310.0
ARMS, FEMALE	450.8	611.6	683.2	934.6	988.4	1090.6	1104.3	1201.3	1310.0
FOREARMS, MALE	237.8	312.9	355.8	478.1	518.7	555.1	567.2	613.1	655.0
FOREARMS, FEMALE	225.4	305.8	341.6	467.3	494.2	545.3	552.2	600.6	655.0
HANDS, MALE	213.6	281.1	319.6	405.0	422.4	452.0	407.0	439.9	470.0
HANDS, FEMALE	202.5	274.7	306.9	395.9	402.4	444.0	396.2	431.0	470.0
LEGS, MALE	935.2	1230.3	1399.0	1784.8	2060.0	2204.5	2346.9	2536.6	2710.0
LEGS, FEMALE	886.2	1202.5	1343.3	1744.5	1962.7	2165.6	2284.5	2485.1	2710.0
THIGHS, MALE	561.1	738.2	839.4	1070.9	1236.0	1322.7	1408.1	1521.9	1626.0
THIGHS, FEMALE	531.7	721.5	806.0	1046.7	1177.6	1299.4	1370.7	1491.0	1626.0
LOWER LEGS, MALE	374.1	492.1	559.6	713.9	824.0	881.8	938.7	1014.6	1084.0
LOWER LEGS, FEMALE	354.5	481.0	537.3	697.8	785.1	866.2	913.8	994.0	1084.0
FEET, MALE	262.0	334.1	428.1	478.1	540.9	578.9	597.5	645.8	690.0
FEET, FEMALE	248.3	326.5	411.1	467.3	515.4	568.7	581.7	632.7	690.0

**TABLE B-2. Age-Specific Skin Surface Area (continued)**

MEDIAN (50th Percentile) AGE-SPECIFIC SKIN SURFACE AREA (cm <sup>2</sup> )									
PART OF THE BODY	9<10	10<11	11<12	12<13	13<14	14<15	15<16	16<17	17<18
TOTAL BODY SURFACE, MALE	10700	11800	12300	13400	14700	16100	17000	17600	18000
TOTAL BODY SURFACE, FEMALE	10600	11700	13000	14000	14800	15500	15700	16000	16300
HEAD, MALE	1284.0	1416.0	1476.0	1171.2	1465.6	1605.2	1353.2	1401.0	1432.8
HEAD, FEMALE	1272.0	1404.0	1560.0	1223.6	1475.6	1545.4	1249.7	1273.6	1297.5
TRUNK, MALE	3659.4	4035.6	4206.6	4649.8	4806.9	5264.7	5559.0	5755.2	5706.0
TRUNK, FEMALE	3625.2	4001.4	4446.0	4858.0	4839.6	5068.5	5133.9	5232.0	5167.1
ARMS, MALE	1316.1	1451.4	1512.9	1835.8	1778.7	1948.1	2057.0	2305.6	3150.0
ARMS, FEMALE	1303.8	1439.1	1599.0	1918.0	1790.8	1875.5	1899.7	2096.0	2852.5
FOREARMS, MALE	658.1	725.7	756.5	917.9	889.4	974.1	1028.5	1152.8	1575.0
FOREARMS, FEMALE	651.9	719.6	799.5	959.0	895.4	937.8	949.9	1048.0	1426.3
HANDS, MALE	567.1	625.4	651.9	723.6	749.7	821.1	867.0	1003.2	918.0
HANDS, FEMALE	561.8	620.1	689.0	756.0	754.8	790.5	800.7	912.0	831.3
LEGS, MALE	3070.9	3386.6	3530.1	4087.0	4704.0	5152.0	5440.0	5913.6	5544.0
LEGS, FEMALE	3042.2	3357.9	3731.0	4270.0	4736.0	4960.0	5024.0	5376.0	5020.4
THIGHS, MALE	1842.5	2032.0	2118.1	2452.2	2822.4	3091.2	3264.0	3548.2	3326.4
THIGHS, FEMALE	1825.3	2014.7	2238.6	2562.0	2841.6	2976.0	3014.4	3225.6	3012.2
LOWER LEGS, MALE	1228.4	1354.6	1412.0	1634.8	1881.6	2060.8	2176.0	2365.4	2217.6
LOWER LEGS, FEMALE	1216.9	1343.2	1492.4	1708.0	1894.4	1984.0	2009.6	2150.4	2008.2
FEET, MALE	813.2	896.8	934.8	938.0	1176.0	1288.0	1360.0	1214.4	1314.0
FEET, FEMALE	805.6	889.2	988.0	980.0	1184.0	1240.0	1256.0	1104.0	1189.9

**TABLE B-2. Age-Specific Skin Surface Area (continued)**

PART OF THE BODY	MEDIAN (50th Percentile) AGE-SPECIFIC SKIN SURFACE AREA (cm <sup>2</sup> )					
	18<25	25<35	35<45	45<55	55<65	65<75
TOTAL BODY SURFACE, MALE	19400	19400	19400	19400	19400	19400
TOTAL BODY SURFACE, FEMALE	16900	16900	16900	16900	16900	16900
HEAD, MALE	1300	1300	1300	1300	1300	1300
HEAD, FEMALE	1110	1110	1110	1110	1110	1110
TRUNK, MALE	7390	7390	7390	7390	7390	7390
TRUNK, FEMALE	5790	5790	5790	5790	5790	5790
ARMS, MALE	2910	2910	2910	2910	2910	2910
ARMS, FEMALE	2300	2300	2300	2300	2300	2300
FOREARMS, MALE	1455	1455	1455	1455	1455	1455
FOREARMS, FEMALE	1150	1150	1150	1150	1150	1150
HANDS, MALE	990	990	990	990	990	990
HANDS, FEMALE	817	817	817	817	817	817
LEGS, MALE	6400	6400	6400	6400	6400	6400
LEGS, FEMALE	5460	5460	5460	5460	5460	5460
THIGHS, MALE	3820	3820	3820	3820	3820	3820
THIGHS, FEMALE	3260	3260	3260	3260	3260	3260
LOWER LEGS, MALE	2560	2560	2560	2560	2560	2560
LOWER LEGS, FEMALE	2180	2180	2180	2180	2180	2180
FEET, MALE	1310	1310	1310	1310	1310	1310
FEET, FEMALE	1140	1140	1140	1140	1140	1140

## C. Soil Ingestion Rate

Soil ingestion is assumed to occur incidentally, from hand-to-mouth contact, during outdoor activities in the warmer months of the year (April through October). Soil from outdoors can also be brought indoors (e.g., on clothing, shoes and tools) or can enter the house as windblown dust. Therefore, some incidental soil/dust ingestion can also occur indoors.

The risk assessor has the option of evaluating soil exposures in greater detail than the approach presented here. For a discussion on how soil exposures can be evaluated in a more detailed manner, refer to the *Methodology For Relating Soil Contaminant Levels and Risk to Human Health* (MADEP, 1995).

Default daily soil ingestion rates are presented in Table B-3. Table B-3 provides a soil ingestion rate for children aged 1 < 6 years and a rate for children and adults older than six years. It is presumed that, under most circumstances, the majority of incidental soil ingestion will be received from indoor and outdoor exposures during the warmer months of the year. The soil ingestion rates provided in Table B-3 can be assumed to adequately represent the sum of outdoor and indoor soil exposures on days when exposure occurs.

Table B-3 also includes a default soil ingestion rate for an enhanced (or more intense) exposure. The enhanced soil ingestion rate should be used for adult receptors who are exposed to soil at a more intense rate (e.g., a construction worker digging a ditch). This higher rate is not intended for estimating soil intake for children suffering from pica (such exposures are assumed to be greater than the intake rates presented here).

**TABLE B-3. Daily Soil Ingestion Rates**

AGE (years)	INGESTION RATE (mg of soil per day)
1 < 6	100
> 6	50
Enhanced Exposure	500

Soil ingestion rates should always be used as **daily** rates. It is **not** appropriate to modify the soil ingestion rate to account for an exposure which occurs for a portion of a day as the studies on which the soil ingestion rates are based do not indicate whether soil ingestion is a sporadic event or whether it occurs evenly throughout the exposure period.

Given the absence of data specific to the ingestion of sediment, the soil ingestion rates provided in Table B-3 may be used to evaluate sediment ingestion. It is ORS's view that the use of such values is not likely to underestimate exposures from ingestion of sediment.

Sources:

Hawley, J.K. (1985) *Assessment of Health Risk from Exposure to Contaminated Soil*, *Risk Analysis*, Vol. 5: 289-302.

LaGoy, P.K. (1987) *Estimated Soil Ingestion Rates for Use in Risk Assessment*, *Risk Analysis*, Vol. 7 No. 3: 355-359.

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

U.S. EPA, Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, (1989).

## D. Drinking Water Ingestion Rate

The following drinking water consumption rates for adults and children are standard assumptions recommended by the U.S. EPA.

Adult.....2 liters water/day  
Child.....1 liter water/day

Sources:

US EPA, Exposure Factors Handbook -- Final Report, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA/600/8-89-0430] (March 1989).

US EPA, Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors, U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response [OSWER Directive 9285.6-03] (1991).

## E. Respiratory Volume

Table B-4 provides age-specific, average minute ventilation rates (inspired or expired volume of air per minute, expressed as liters per minute) for 3 different activity levels: low activity; light exertion; and heavy exertion. Air intakes as liters per minute can be converted to the more commonly expressed intake in cubic meters per hour by multiplying by 60 (minutes to hours) and 1/1000 (liters to cubic meters).

Sources:

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

Phalen, R.F.; Oldham, M.J.; Beaucage, C.B.; Crocker, T.T. and Mortensen, J.D. (1985) *Postnatal Enlargement of Human Tracheobronchial Airways and Implications for Particle Deposition*, *Anat. Rec.* 212: 368-380.

U.S. EPA, Review of the National Ambient Air Quality Standards for Lead: Assessment of Scientific and Technical Information, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, (1989).

**TABLE B-4. Age-specific Average Minute Ventilation Rates**

AGE (Years)	MINUTE VENTILATION (liters per minute)		
	Low Activity	Light Exertion	Heavy Exertion
<1	1.52	3	8.92
1<2	1.52	3	8.92
2<3	2.75	5.48	16.40
3<4	2.75	5.48	16.40
4<5	3.18	6.34	19.00
5<6	3.18	6.34	19.00
6<7	3.89	7.77	23.20
7<8	3.89	7.77	23.20
8<9	4.53	9.05	27.10
9<10	4.53	9.05	27.10
10<11	5.42	10.80	32.40
11<12	5.42	10.80	32.40
12<13	6.56	13.10	39.3
13<14	6.56	13.10	39.3
14<15	7.96	15.90	47.8
15<16	7.96	15.90	47.8
16<17	9.10	18.20	54.6
17<18	9.10	18.20	54.6
18<75	10.00	20.00	60.00

## F. Airborne Particulate Concentration

The mass of soil in air may be expressed in terms of Total Suspended Particles (TSP) or particles with a defined size distribution (e.g., PM10). The "10" in PM10 refers to the upper limit of the particle aerodynamic diameter, i.e. 10 micrometers. Data collected by the Massachusetts Department of Environmental Protection's Division of Air Quality Control indicates that 40% of the TSP mass is in particles with diameters less than 10 micrometers (PM10). Particle sizes of greatest concern for respiratory effects are contained in the PM10 mass.

Default values for the ambient PM10 concentration are provided for two scenarios. The first scenario is an open field situation, in which contaminated soil is sparsely vegetated or bare, and soil particulate matter readily becomes airborne. The second situation is a grading, or excavation scenario, in which earth working activities may raise greater levels of dust.

Open Field: PM10 =  $32 \mu\text{g}/\text{m}^3$   
Excavation: PM10 =  $60 \mu\text{g}/\text{m}^3$

The value for the default PM10 concentration for an open field scenario is the highest annual arithmetic mean PM10 concentration recorded from among 17 state operated sampling stations in Massachusetts in 1994. (The seventeen annual arithmetic means from these sampling stations ranged from 12 to  $32 \mu\text{g}/\text{m}^3$ .) In most cases, it is appropriate to assume that 100% of the PM10 is soil-derived. However, as an area becomes more heavily vegetated, is less likely that soil particulate matter will become airborne. On a site-specific basis, with appropriate justification, the percentage of PM10 that is soil-derived may be reduced to as low as 40% (Thurston and Spengler, 1983).

The default PM10 concentration for an excavation scenario represents the arithmetic mean of the 24-hour maximum PM10 values from 17 sampling locations in the Commonwealth during 1993. (The twenty maximum values from these 17 locations - 3 stations had collocated samplers - ranged from 40 to  $97 \mu\text{g}/\text{m}^3$ .) It should be assumed that 100% of the PM10 is soil-derived.

### Sources:

MA DEP, 1993 Air Quality Report, Massachusetts Department of Environmental Quality Engineering, Division of Air Quality Control (1994).

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

Thurston, G.D. and Spengler, J.D. (1983) *Mass and Elemental Composition of Fine and Course Particles in Six Cities*, J. Air Pollution Control Assoc. 33:1162-1171.

## G. Soil Adherence Factor

The amount of soil adhering to the skin varies according to soil particle size with finer particles giving a denser coating. A soil adherence value for typical exposure to outdoor soil is provided below.

$$\text{Soil adherence factor} = 0.51 \text{ mg soil/cm}^3 \text{ skin}$$

This value is taken from a 1985 article by J.K. Hawley and is based on quantitative measurements of the amount of soil adhering to the hands of children aged 2 to 6 years. This value is also within the U.S. EPA's recommended range of 0.2 to 1 mg/cm<sup>2</sup> for soil-skin adherence expected under actual human exposure conditions. When exposure to contaminated outdoor soil is being assessed, a soil adherence factor of 0.51 mg soil/cm<sup>3</sup> skin should be used.

The risk assessor may want to evaluate soil exposures in a more detailed manner. Refer to the Draft *Methodology For Relating Soil Contaminant Levels and Risk to Human Health* (MADEP, 1995) for information on a more detailed methodology for evaluating soil exposures.

### Sources:

Hawley, J.K. (1985) *Assessment of Health Risk from Exposure to Contaminated Soil*, Risk Analysis, Vol. 5: 289-302.

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

US EPA, Dermal Exposure Assessment: Principles and Application, U.S. Environmental Protection Agency, Exposure Assessment Group, Office of Health and Environmental Assessment [EPA/600/8-91/011B] INTERIM REPORT (January 1992).

## H. Sediment Adherence Factor

Although the soil adherence factor was derived based on exposure to soil, it has been used as a default value in assessing exposures to sediments. However, because dermal exposure to sediment can differ from exposure to soil, the risk assessor should be aware that using the soil adherence factor for sediment exposures could lead to a potential over or underestimate of dermal dose.

Dermal exposure to sediment typically occurs along the banks of rivers or ponds where there is repetitive skin contact with sediment and water which results in sediment being

repeatedly applied and removed. Using the adherence factor developed for soil could either underestimate or overestimate the dose because of the two factors detailed below.

Sediment that is repeatedly applied and washed or rubbed off the skin during wading in surface water or mud results in a shorter period of contact between the sediment and the skin than if the sediment is applied once and left on the skin throughout the entire exposure period. Using the adherence factor developed for soil in this exposure situation could overestimate the true dose from the initially contacted sediment.

When a chemical first contacts the skin, more of it enters that skin than exits into the body. Repeated application of new sediment to the skin could potentially lead to a greater dose than would be the case if the sediment is applied once and remains on the skin throughout the entire exposure period. Using the adherence factor developed for soil in this exposure situation could underestimate the true dose from repeated skin contact with contaminated sediment.

However, recognizing these limitations and in the absence of site-specific or otherwise justifiable exposure information, the soil adherence factor can be used for assessing dermal exposures to sediments.

Sources:

Hawley, J.K. (1985) *Assessment of Health Risk from Exposure to Contaminated Soil*, Risk Analysis, Vol. 5: 289-302.

US EPA, Dermal Exposure Assessment: Principles and Application, U.S. Environmental Protection Agency, Exposure Assessment Group, Office of Health and Environmental Assessment [EPA/600/8-91/011B] INTERIM REPORT (January 1992).

## I. Food Consumption

Much of the information regarding food consumption is based on data collected during the Nationwide Food Consumption Survey conducted by the U.S. Department of Agriculture (USDA) in 1977-1978. It is important to note that these data represent national food consumption patterns in 1977-1978. It is likely that intakes for some food products may be different today. Moreover, the types of food and rates of intake are highly influenced by cultural and geographic factors. Thus, the risk assessor should be particularly attentive to local and cultural variations in food intake rates. To the extent possible, site-specific intake rates should be used. In the absence of site-specific values, the default values provided below should be used.

### 1. Freshwater Fish

The default consumption rate provided below is taken from a mail survey of licensed anglers in Maine (Ebert et al, 1993).

Sport-caught freshwater fish = 26 g/day

The default value represents the 95<sup>th</sup> percentile consumption rate for sport-caught fish from flowing and standing fresh waterbodies (i.e., rivers, streams, lakes and ponds). The default consumption rate assumes that fish obtained by anglers are shared equally with other household members who consume fish. The consumption rate equates to roughly one ounce of fish per day or one 8 ounce fish meal 3 or 4 times per month.

This default fish consumption rate should be used when evaluating fish intake by sportfishermen (and sportfisherwomen!). The risk assessment should evaluate exposure to those recreational anglers who use the fishery resource to its fullest extent. Evaluation of this receptor group is consistent with Section 40.0923 of the MCP which provides that the risk characterization should describe the full extent of site activities consistent with an identified site use. In this situation, the site use is catching and consuming fish and the risk characterization should evaluate individuals who consume fish to the fullest extent. In other words, the evaluation of exposure to sportfishers from ingesting contaminated fish should focus on the subgroup of anglers who eat a relatively large amount of fish from the waterbody of concern.

The fish consumption rate should represent an average or typical intake rate for this high-use group. Therefore, a population average (for all sportfishermen) would not be representative of exposures to high-use individuals. The ideal way to obtain a high-use average is to calculate the average of all the consumption rates that fall at the high end of the sportfishing population intake range (for example, above the 80th percentile). The Department plans to use the raw data from the Ebert et al. study described above to calculate an average fish consumption rate for the high-end of the sportfishing population. Until the Department provides such a value, it is recommending using the 95<sup>th</sup> percentile fish consumption rate (26 g/person/day) from the Ebert et al. study, as described above.

Note: EPA's Exposure Factors Handbook provides a value of 6.5 g/day as an average per capita nonmarine fish consumption rate. This value was established by EPA in setting the Ambient Water Quality Criteria. However, EPA states that this value underestimates actual consumption rates for recreational fisherman and is not accurate to use when assessing exposure to recreational fishermen at a specific site. The Ebert *et al.* study of Maine anglers provides a similar average consumption rate of 6.4 g/day (for fish from rivers, streams, lakes and ponds).

EPA's Exposure Factors Handbook also provides a 50<sup>th</sup> percentile value of 30 g/day and a 90<sup>th</sup> percentile value of 140 g/day as values which it considers to be representative of consumption rates for recreational anglers (both marine

and freshwater). Although these values come from studies on the west coast of the United States, EPA recommends that these values be used to represent consumption rates for recreational fisherman in any area where there is a large water body present and widespread contamination is evident.

It is the Department's view that 26 g/day (the 95<sup>th</sup> percentile fish consumption rate in the Ebert *et al.* study) represents the most appropriate default consumption rate for recreational *freshwater* fish consumption in Massachusetts. However, the risk assessor should be attentive to local and cultural variations in fish consumption. To the extent possible, site-specific intake rates should be used which represent consumption of fish by anglers who make full use of a waterbody for fishing.

Sources:

Ebert, E., Boyle, K., Knight, J. and Keenan, R. (1993) *Estimating Consumption of Freshwater Fish among Maine Anglers*, *North American Journal of Fisheries Management*, 13:757-745.

US EPA, *Exposure Factors Handbook -- Final Report*, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA/600/8-89-0430] (March 1989).

***PROGRAM/POLICY NOTE: The Bureau of Waste Site Cleanup (BWSC) is evaluating whether the derivation of the default value described above is consistent with program and policy goals. Any change to this guidance will be posted on the MADEP Bulletin Board System.***

## **2. Mother's Milk**

The default intake rate for mothers milk is taken from Report No. 76, published by the National Council on Radiation Protection and Measurements.

Infant's Daily Intake of Mother's Milk = 696 ml/day

Source:

National Council on Radiation Protection and Measurement, Radiological Assessment: Predicting the Transport, Bioaccumulation, and Uptake by Man of Radionuclides Releases to the Environment, NCRP Report No. 76, (March 1984).

## **3. Home-Produced Dairy Products and Grains**

EPA's Exposure Factors Handbook provides the following average consumption rates for home-produced dairy products as a whole and for fresh milk. These values assume that 40% of the amount consumed is home-produced.

Average consumption rates for homegrown eggs and grains are taken from the U.S. Nuclear Regulatory Commission document cited below.

Dairy products = 160 g/day

Fresh milk = 120 g/day

Eggs = 27.4 g/day

Grains = 190 g/day

Sources:

US EPA, Exposure Factors Handbook -- Final Report, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA/600/8-89-0430] (March 1989).

U.S. Nuclear Regulatory Commission, Residual Radioactive Contamination From Decommissioning - Technical Basis for Translating Contamination Levels to Annual Total Effective Dose Equivalent, W.E. Kennedy and D.L. Strenge, Pacific Northwest Laboratory, Final Report, Vol. 1; [NUREG/CR-5512] (October 1992).

#### **4. Homegrown Produce**

Intake rates for homegrown produce are based on market basket information gathered by the U.S. Department of Agriculture in the 1977-78 USDA Nationwide Food Consumption Survey and on data used by the U.S. EPA for assessing the land application of municipal sludge. Nineteen garden fruits and vegetables are included in the market basket and the average daily consumption rates for the *homegrown* fruits or vegetables were calculated for different age groups as described below.

Table B-5 provides the proportion of produce ingested that is homegrown. The relationship between the amount of homegrown produce and total ingested produce is described by subtracting the amount (lbs/week) of produce purchased from the total amount of produce eaten (E). The amount eaten is based on an average family size of 3.06 members per household in the USDA survey. The difference (D) is assumed to be homegrown. The ratio D/E give the proportion of the total intake which should be considered to be homegrown. This information is specific to households in the New England states. The population considered was made up of families in all types of urbanization (central city, suburban and non-metropolitan). The intakes were averaged over the entire year.

The total produce intakes (purchased plus homegrown) were identified by EPA for four age groups: 0.5 to 1 year old, 2 years old, 14 to 16 years old, and 26 to 30 years old. These produce-specific intakes are given in dry weight, and are listed in Table B-6.

The average daily intake of homegrown produce was estimated for each type of fruit and vegetable by multiplying the proportion of homegrown to total (from Table B-5) by the total intake (Table B-6) of each type of produce. The results are shown in Table B-7.

Homegrown produce intake rates that are specific to families in rural areas are also available from the USDA survey and the EPA municipal sludge report. It may be appropriate to use produce intakes for rural families instead of the intakes presented in Tables B-5 through B-7 in locations (such as agricultural areas) where one would expect homegrown produce intake to be higher. Refer to the Draft *Methodology For Relating Soil Contaminant Levels and Risk to Human Health* (MADEP, 1995) for homegrown produce intakes for rural populations.

**TABLE B-5 PROPORTION OF FRESH PRODUCE THAT IS HOMEGROWN  
FOR THE GENERAL POPULATION  
(Northeastern U.S.)**

PRODUCE	Amount Eaten (E) (lbs/wk)	Amount Bought (lbs/wk)	Difference (D) (lbs/wk)	Proportion D/E
White Potato	2.94	2.77	0.17	0.0578
Lettuce	1.27	1.22	0.05	0.0394
Spinach	0.08	0.07	0.01	0.1250
Cabbage	0.54	0.48	0.06	0.1111
Broccoli	0.23	0.22	0.01	0.0435
Cauliflower	0.09	0.08	0.01	0.1111
Peppers	0.26	0.22	0.04	0.1538
Beans (wax)	0.28	0.16	0.12	0.4286
Peas	0.04	0.02	0.02	0.5000
Beets	0.06	0.01	0.05	0.8333
Carrots	0.46	0.41	0.05	0.1087
Onions	0.60	0.55	0.05	0.0833
Corn	0.56	0.40	0.16	0.2857
Cucumbers	0.50	0.38	0.12	0.2400
Pumpkin, Squash	0.21	0.10	0.11	0.5238
Strawberries	0.11	0.09	0.02	0.1818
Tomatoes	1.14	0.66	0.48	0.4211
Cantaloupe	0.59	0.54	0.05	0.0847
Other Berries	0.06	0.03	0.03	0.5000

**TABLE B-6**  
**AVERAGE DAILY INTAKE OF PRODUCE FOR THE GENERAL POPULATION**

AVERAGE DAILY INTAKE OF PRODUCE (Dry Weight)				
Produce	Total Intake 0.5 < 1 yr (g/day)	Total Intake 2 year old (g/day)	Total Intake 14 < 16 yr (g/day)	Total Intake 26 < 30 yr (g/day)
White Potato	0.8390	2.4001	3.8646	4.2338
Lettuce	0.0053	0.1071	0.5466	0.9468
Spinach	0.0160	0.0470	0.0470	0.2700
Cabbage	0.0143	0.0539	0.1900	0.3600
Broccoli	0.0300	0.1100	0.1400	0.0582
Cauliflower	0	0.0271	0.0283	0.0700
Peppers	0.0005	0.0046	0.0200	0.1878
Beans (wax)	0.0278	0.0724	0.0967	0.3000
Peas	0.1700	0.1200	0.1600	0.0976
Beets	0.0021	0.0371	0.0806	0.6109
Carrots	0.2016	0.3993	0.3340	0.3065
Onions	0.0206	0.0606	0.3391	1.5300
Corn	0.1000	1.04	2.0900	0.1700
Cucumbers	0.0070	0.0380	0.0870	0.2773
Pumpkin, Squash	0.1264	0.0590	0.1153	0.1900
Strawberries	0.0500	0.1200	0.1600	1.1263
Tomatoes	0.0627	0.3462	0.6887	0.2824
Cantaloupe	0.0561	0.0631	0.3010	0.0114
Other Berries	0.0005	0.0082	0.0110	

**TABLE B-7 AVERAGE DAILY INTAKE OF HOMEGROWN PRODUCE  
FOR THE GENERAL POPULATION  
(Dry Weight)**

AVERAGE DAILY INTAKE OF <u>HOMEGROWN</u> PRODUCE				
	Homegrown Intake	Homegrown Intake	Homegrown Intake	Homegrow n Intake
Produce	0.5 < 1 yr (g/day)	2 year old (g/day)	14 < 16 yr (g/day)	26 < 30 yr (g/day)
White Potato	0.0485	0.1387	0.2234	0.2447
Lettuce	0.0002	0.0042	0.0213	0.0369
Spinach	0.0020	0.0059	0.0059	0.0250
Cabbage	0.0016	0.0060	0.0211	0.0300
Broccoli	0.0013	0.0047	0.0060	0.0155
Cauliflower	0	0.0030	0.0031	0.0065
Peppers	0.0001	0.0007	0.0031	0.0108
Beans (wax)	0.0119	0.0311	0.0415	0.0806
Peas	0.0850	0.0600	0.0800	0.1500
Beets	0.0017	0.0309	0.0671	0.0813
Carrots	0.0220	0.0435	0.0364	0.0666
Onions	0.0017	0.0050	0.0281	0.0254
Corn	0.0286	1.2974	0.5977	0.4376
Cucumbers	0.0017	0.0091	0.0209	0.0408
Pumpkin, Squash	0.0662	0.0309	0.0604	0.1453
Strawberries	0.0091	0.0218	0.0291	0.0346
Tomatoes	0.0264	0.1458	0.2899	0.4742
Cantaloupe	0.0048	0.0054	0.0256	0.0240
Other Berries	0.0003	0.0041	0.0055	0.0057

Table B-8 provides uptake rates of common contaminants from soil by plants. The accumulation of different chemicals has been reviewed extensively in studies of potential effects of sewage sludge application on cropland. Many of the uptake factors were taken from such reviews. One such source is EPA's Risk Assessment Methodology for Land Application and Distribution and Marketing of Municipal Sludge. That document contains experimental data from several sources for many different types of produce. Uptake factors are based on the concentration of chemical in the portion of the plant that is usually consumed by humans.

Sources:

Bales *et al.* (1984) A Review and Analysis of Parameters for Assessing Transport of Environmentally Released Radionuclides through Agriculture, Bales, C.F., Sharp, R.D., Sjoeren, A.L., and Shor, R.W., Oak Ridge National Laboratories [ORNL-5786], (September 1984).

Cary, E.E. and Kubota, J. (1990) *Chromium Concentration in Plants: Effects of Soil Chromium Concentration and Tissue Contamination by Soil*, *J. Agric. Food Chem.* 38:108-114.

Chaney, R.L., Ryan, J.A. and O'Connor, G.A. (1990) *Risk Assessment for Organic Micropollutants: U.S. Point of View*, Proc. EEC symposium titled "Treatment and Use of Sewage Sludge and Liquid Agricultural Wastes", held in Athens, Greece.

Grant, C. and Dobbs, A.J. (1977) *The Growth and Metal Content of Plants Grown In Soil Contaminated by a Copper/Chrome/Arsenic Wood Preservative*, *Environmental Pollution* 14:213-226.

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

Rinne, R.J. (1986) Soil Clean Up Guidelines for Decommissioning of Industrial Lands - Background and Rationales for Development, Ontario Ministry of the Environment.

United States Department of Agriculture; *Food Consumption in the Northeast, Seasons and Year 1977-78*, United States Department of Agriculture Consumer Nutrition Division [Report H-7] (August 1983).

US EPA, *Development of Risk Assessment Methodology for Land Application and Distribution and Marketing of Municipal Sludge*; U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA 600/6-89/001] (1989).

Walsh, L.M., Sumner, M.E. and Keeney, D.R. (1977) *Occurrence and Distribution of Arsenic in Soils and Plants*, *Environmental Health Perspectives* 19:67-71.

TABLE B-8 PLANT UPTAKE FACTORS

PLANT UPTAKE FACTORS						
$(\text{mg}_{\text{chemical}}/\text{kg}_{\text{dry wt. plant}}) \text{ per } (\text{mg}_{\text{chemical}}/\text{kg}_{\text{dry wt. soil}})$						
(References)						
Produce	ARSENIC	CADMIUM	CHROMIUM	LEAD	MERCURY	NICKEL
White Potato	0.0006	0.03	0.11 (1)	0.0008	0.0033	0.125
Lettuce	0.04	0.43	0.0075 (2)	0.008	0.007	0.09
Spinach	0.04	0.43	0.0075 (3)	0.008	0.007	0.09
Cabbage	0.04	0.43	0.0075 (2)	0.008	0.007	0.09
Broccoli	0.04	0.43	0.0075 (2)	0.008	0.007	0.09
Cauliflower	0.04	0.43	0.0075 (2)	0.008	0.007	0.09
Peppers	0.002	0.05	0.01 (2,4)	0.002	0.0033	0.04
Beans (wax)	0.0002	0.01	0.81 (1)	0.001	0.001	0.13
Peas	0.0002	0.01	0.81 (1)	0.001	0.001	0.13
Beets	0.02	0.22	0.0125 (5)	0.003	0.017	0.52
Carrots	0.02	0.22	0.0125 (5)	0.003	0.017	0.52
Onions	0.02	0.22	0.0125 (5)	0.003	0.017	0.52
Corn	0.0001	0.03	0.0125 (5)	0.01	0.0033	0.13
Cucumbers	0.002	0.05	0.0125 (5)	0.002	0.0033	0.04
Pumpkin, Squash	0.002	0.05	0.0125 (5)	0.002	0.0033	0.04
Strawberries	0.002	0.05	0.0125 (5)	0.002	0.0033	0.04
Tomatoes	0.002	0.05	0.0125 (5)	0.002	0.0033	0.04
Cantaloupe	0.002	0.05	0.0125 (5)	0.002	0.0033	0.04
Other Berries	0.002	0.05	0.0125 (5)	0.002	0.0033	0.04
All uptake factors taken from U.S. EPA (1989d) <u>unless</u> otherwise noted:						
(1) -	Grant, 1977					
(2) -	Baes, 1984					
(3) -	Walsh, 1977					
(4) -	Cary, 1990					
(5) -	Rinne, 1986					

TABLE B-8 PLANT UPTAKE FACTORS *continued*

PLANT UPTAKE FACTORS					
$(\text{mg}_{\text{chemical}}/\text{kg}_{\text{dry wt. plant}}) \text{ per } (\text{mg}_{\text{chemical}}/\text{kg}_{\text{dry wt. soil}})$					
(References)					
Produce	SILVER	THALLIUM	ZINC	PAHs	PCBs
White Potato	0.8 (5)	0.0004 (2)	0.02	0.42	0.02 (6)
Lettuce	0.8 (5)	0.0004 (2)	0.8	0.29	0.38 (6)
Spinach	0.8 (5)	0.0004 (2)	0.8	0.29	0.38 (6)
Cabbage	0.8 (5)	0.0004 (2)	0.8	0.29	0.38 (6)
Broccoli	0.8 (5)	0.0004 (2)	0.8	0.29	0.38 (6)
Cauliflower	0.8 (5)	0.0004 (2)	0.8	0.29	0.38 (6)
Peppers	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
Beans (wax)	0.8 (5)	0.0004 (2)	0.04	0.42	0.002 (6)
Peas	0.8 (5)	0.0004 (2)	0.04	0.42	0.002 (6)
Beets	0.8 (5)	0.0004 (2)	0.05	0.61	0.36 (6)
Carrots	0.8 (5)	0.0004 (2)	0.05	0.61	0.36 (6)
Onions	0.8 (5)	0.0004 (2)	0.05	0.61	0.36 (6)
Corn	0.8 (5)	0.0004 (2)	0.04	0.42	0 (6)
Cucumbers	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
Pumpkin, Squash	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
Strawberries	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
Tomatoes	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
Cantaloupe	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
Other Berries	0.8 (5)	0.0004 (2)	0.04	0.42	0.02 (6)
All uptake factors taken from U.S. EPA (1989d) <u>unless</u> otherwise noted:					
(2) -	Baes, 1984				
(5) -	Rinne, 1986				
(6) -	Chaney, 1990				

TABLE B-8 PLANT UPTAKE FACTORS *continued*

PLANT UPTAKE FACTORS						
(mg <sub>chemical</sub> /kg <sub>dry wt. plant</sub> ) per (mg <sub>chemical</sub> /kg <sub>dry wt. soil</sub> )						
(References)						
Produce	SELENIUM	ALDRIN/ DIELDRIN	DDT/DDE DDD	HEPTACHLOR	HEXACHLORO -BENZENE	TOXAPHENE
White Potato	0.02	0.13	0.07	0.3	0.75	0.27
Lettuce	0.07	0.2	0.11	0.02	0.56	0.07
Spinach	0.07	0.2	0.11	0.02	0.56	0.07
Cabbage	0.07	0.2	0.11	0.02	0.56	0.07
Broccoli	0.07	0.2	0.11	0.02	0.56	0.07
Cauliflower	0.07	0.2	0.11	0.02	0.56	0.07
Peppers	0.04	0.22	0.11	0.21	0.78	0.07
Beans (wax)	0.02	0.81	0.04	0.04	0.78	0.07
Peas	0.02	0.81	0.04	0.04	0.78	0.07
Beets	0.04	0.43	0.11	2.71	1.11	1.73
Carrots	0.04	0.43	0.11	2.71	1.11	1.73
Onions	0.04	0.43	0.11	2.71	1.11	1.73
Corn	0.03	0.02	0.51	0.14	0.78	0.07
Cucumbers	0.04	0.22	0.11	0.21	0.78	0.07
Pumpkin, Squash	0.04	0.22	0.11	0.21	0.78	0.07
Strawberries	0.04	0.22	0.11	0.21	0.78	0.07
Tomatoes	0.04	0.22	0.11	0.21	0.78	0.07
Cantaloupe	0.04	0.22	0.11	0.21	0.78	0.07
Other Berries	0.04	0.22	0.11	0.21	0.78	0.07
All uptake factors taken from U.S. EPA (1989d) <u>unless</u> otherwise noted.						

## 5. Homegrown Meat and Poultry

The consumption rate for homegrown beef is taken from EPA's Exposure Factors Handbook. Based upon USDA studies, in households where beef is homegrown, the average percent of annual consumption of beef that is homegrown is 44%. Since the total amount of beef consumed averages approximately 100 g/day, it can be estimated that 44 % of this amount, 44 g/day, represents the average consumption rate for homegrown beef.

The average homegrown poultry consumption rate is taken from the U.S. Nuclear Regulatory Commission publication cited below.

Homegrown Poultry Intake = 25 g/day

### Sources:

MA DEP, Methodology for Relating Soil Contaminant Levels and Risk to Human Health, Massachusetts Department of Environmental Protection, Office of Research and Standards DRAFT (March 1995).

US EPA, Exposure Factors Handbook -- Final Report, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment [EPA/600/8-89-0430] (March 1989).

U.S. Nuclear Regulatory Commission, Residual Radioactive Contamination From Decommissioning - Technical Basis for Translating Contamination Levels to Annual Total Effective Dose Equivalent, W.E. Kennedy and D.L. Streng, Pacific Northwest Laboratory, Final Report, Vol. 1; [NUREG/CR-5512] (October 1992).

## **J. Showering/Bathing and Swimming Exposures**

### 1. Inhalation Exposures during Showering

Exposures via inhalation are generally important only for volatile organic compounds (VOCs) and known specific volatile materials which are not VOCs. Inhalation exposures to nonvolatile organic and inorganic compounds during showering are generally assumed to be negligible and do not need to be evaluated unless the chemical under investigation is significantly more toxic when inhaled than when ingested.

For VOCs, there is evidence that inhalation exposures in the shower environment may result in absorbed doses equal to and no greater than doses associated with ingesting the same water.

The default approach for assessing inhalation exposures to VOCs during showering is to assume that the dose received during showering is equal to the dose that would be received from ingesting the same water. Based on this assumption, risks from inhalation are assessed using the ingested dose (converted to an applied dose) with

appropriate inhalation toxicity values. Refer to Section 7.3.4.4. for a more detailed discussion on estimating inhalation exposures during showering.

As an alternative to the default approach, the risk assessor may choose to estimate the inhalation exposure per shower using a shower model such as the Foster and Chrostowski shower model. Table B-9 below provides default input values for use in the Foster and Chrostowski model. Values are taken from Foster and Chrostowski (1987) except where noted. If a different model is used, all input values should be clearly provided in the Risk Assessment.

**TABLE B-9**  
**DEFAULT INPUT VALUES FOR FOSTER & CHROSTOWSKI SHOWER MODEL**

Model Parameter	Definition	Value	(Scenario Specific)
$T_s$	Shower water temperature	318° K	
$\mu_s$	Water viscosity at $T_s$	0.596 cp	
d	Shower droplet diameter	1 mm	
$t_s$	Shower droplet drop time	2 sec	
FR	Shower water flow rate	10 l/min	
SV	Shower room air volume	6 m <sup>3</sup>	
R	Air exchange rate	0.00833 l/min	
$D_s$	Shower duration	15 min	(Scenario)
$D_t$	Total duration in shower room	20 min	(Scenario)
$R_{gc}$	Gas constant	$8.2 \times 10^{-5}$ atm-m <sup>3</sup> /mol-°K	
$T_a$	Absolute temperature	293° K	
$k_g$ (H <sub>2</sub> O)	gas-film mass transfer coefficient	3000 cm/hr	
$k_g$ (CO <sub>2</sub> )	liquid-film mass transfer coefficient	20 cm/hr	
$T_1$	Calibration water temperature	293° K	
$\mu_1$	Water viscosity at $T_1$	1.002 cp	
VR (adult)	Ventilation rate	15 l/min	(Scenario)
BW (adult)	Body weight	62 kg	(Scenario)

## 2. Dermal Exposures During Showering/Bathing and Swimming

The default approach for assessing dermal exposures during showering/bathing and swimming assumes steady-state conditions throughout the exposure period and involves calculating an average daily dermal dose using a chemical-specific permeability coefficient ( $K_p$ ). Experimentally-derived  $K_p$  values are available for some organic and inorganic compounds. EPA has developed  $K_p$  values for many organic compounds using a statistical algorithm based on experimentally measured  $K_p$  values (Potts and Guy, 1992). The Potts and Guy equation is discussed in EPA's Interim Report entitled *Dermal Exposure Assessment: Principles and Applications*. The uncertainty in EPA's estimated  $K_p$  values are judged by EPA to be within plus or minus one order of magnitude. Table B-10 below provides measured and estimated  $K_p$  values for many compounds. When a measured and estimated  $K_p$  value is available for a compound, the measured value should be used.

A default  $K_p$  of  $10^{-3}$  cm/hr may be used for inorganic chemical for which there is no measured value. This default value is recommended by EPA in the its Interim Report on Dermal Exposure Assessment.

Note: The Department has not adopted EPA's non-steady state scheme, developed by Cleek and Bunge (1992) and described in EPA's Interim Report, for evaluating the dermal dose absorbed from water because this approach is still under review by the scientific community and preliminary testing by EPA has shown that it may result in an overconservative total absorbed dose.

## 3. Ingestion Exposures during Swimming

A default value for incidental ingestion of water during swimming is provided below. This value is roughly equivalent to the amount of water in a large adult mouthful or several mouthfuls for a child.

Incidental Ingestion of Water During Swimming = 50 ml/day

### Sources:

Andelman, J.B. (1985) *Inhalation Exposure in the Home to Volatile Organic Contaminants of Drinking Water*, *The Science of the Total Environment*, Vol. 47: 443-460.

Foster, S.A. and Chrostowski, P.C. (1987) *Inhalation Exposures To Volatile Organic Contaminants in the Shower*, presented at the 80th Annual Meeting of APCA, New York, New York, June 21-26, [paper 87-42.6].

US EPA, *Dermal Exposure Assessment: Principles and Application*, U.S. Environmental Protection Agency, Exposure Assessment Group, Office of Health and Environmental Assessment [EPA/600/8-91/011B] **INTERIM REPORT** (January 1992).

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
<b>Organics:</b>		
Acetaldehyde		7.2e-04
Acetamide		1.1e-04
Acetylaminofluorene, 2-		1.7e-02
Acrolein		7.4e-04
Acrylamide		2.4e-04
Acrylonitrile		1.4e-03
Aldrin		1.6e-03
Allyl chloride		7.0e-03
Amino-2-methylantraquinone, 1-		6.6e-03
Aminoanthraquinone, 2-		2.8e-03
Aminoazobenzene, p-		8.7e-03
Aminoazotoluene, o-		4.9e-02
Aminobiphenyl, 4-		1.7e-02
Aniline	4.1e-02	2.2e-03
Anisidine, o-		1.7e-03
Auramine		1.5e-02
Benzene	1.1e-01	2.1e-02
Benzidine		1.3e-03
Benzo-a-anthracene		8.1e-01
Benzo-a-pyrene		1.2e+00
Benzo-b-fluoranthene		1.2e+00
Benzoic acid		7.3e-03
Benzotrichloride		1.5e-02
Benzyl chloride		1.4e-02

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Bis(2-chloroethyl)ether		2.1e-03
Bromodichloromethane		5.8e-03
Bromoform		2.6e-03
Bromomethane		3.5e-03
Bromophenol, p-	3.6e-02	1.3e-02
Butadiene, 1,3-		2.3e-02
Butanediol, 2,3-	5.0e-05	1.2e-04
Butanol, n-	2.5e-03	1.9e-03
Butoxyethanol, 2-	1.2e-02	1.4e-03
Captan		1.3e-03
Carbon disulfide	5.0e-01	2.4e-02
Carbon tetrachloride		2.2e-02
Chlordane		5.2e-02
Chlordane (cis)		4.6e-02
Chlordane (trans)		4.6e-02
Chlorobenzene		4.1e-02
Chlorocresol	5.0e-02	4.1e-02
Chlorodibromomethane		3.9e-03
Chloroethane		8.0e-3
Chloroform	1.3e-01	8.9e-03
Chloromethane		4.2e-03
Chlorophenol, o-	3.3e-02	1.1e-02
Chlorophenol, p-	3.6e-02	1.6e-02
Chlorothalonil		2.5e-02
Chloroxylenol	6.0e-02	3.0e-04
Chrysene		8.1e-01
Cresidine, p-		4.3e-03

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Cresol, m-	1.5e-02	1.0e-02
Cresol, o-	1.6e-02	1.0e-02
Cresol, p-	1.8e-02	1.0e-02
DDD		2.8e-01
DDE		2.4e-01
DDT		4.3e-01
Decanol	8.0e-02	1.7e-01
Di-2-ethylhexyl phthalate		3.3e-02
Diaminoanisole, 2,4-		2.3e-04
Diaminotoluene		6.0e-04
Diaminotoluene, 2,4-		3.3e-03
Dibenzo(a,b)anthracene		2.7e+00
Dibutyl phthalate		3.3e-02
Dichlorobenzene, 1,2-		6.1e-02
Dichlorobenzene, 1,3-		8.7e-02
Dichlorobenzene, 1,4-		6.2e-02
Dichlorobenzidine, 3,3'		1.7e-02
Dichlorodifluoromethane		1.2e-02
Dichloroethane, 1,1-		8.9e-03
Dichloroethane, 1,2-		5.3e-03
Dichloroethylene, 1,1-		1.6e-02
Dichloroethylene, 1,2-(trans)		1.0e-02
Dichlorophenol, 2,4-	6.0e-02	2.3e-02
Dichloropropane, 1,2-		1.0e-02
Dichloropropene, 1,3-		5.5e-03
Dichlorvos		9.5e-04

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Dieldrin		1.6e-02
Diepoxybutane		2.8e-05
Diethyl phthalate		4.8e-03
Diethyl sulfate		1.4e-03
Dimethoxybenzidine, 3,3-		1.0e-03
Dimethyl sulfate		2.2e-03
Dimethylamine, n-nitroso		2.7e-04
Dimethylaminoazobenzene, 4-		1.4e-01
Dimethylbenzidine, 3,3-		4.4e-03
Dimethylcarbaryl chloride		4.2e-04
Dimethylhydrazine, 1,1-		7.1e-05
Dimethylphenol, 2,4-	1.1e-01	1.5e-02
Dimethylphenol, 3,4-	4.0e-02	1.3e-02
Dinitrophenol, 2,4-	3.2e-03	1.8e-03
Dinitrotoluene, 2,4-		3.8e-03
Dinitrotoluene, 2,6-		2.5e-03
Dioxane, 1,4-	4.0e-04	3.6e-04
Diphenylamine, n-nitroso		2.0e-02
Endrin		1.6e-02
Epichlorohydrin		3.7e-04
Ethanol	8.0e-04	6.0e-04
Ethanol, 2-(2-butoxyethoxy)-		4.4e-05
Ethanol, 2-(2-ethoxyethoxy)-		2.5e-04
Ethanol, 2-(2-methoxyethoxy)-		1.8e-04
Ethoxyethanol, 2-	3.0e-04	4.6e-04
Ethoxyethyl acetate, 2-		8.6e-04

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Ethyl acrylate		4.0e-03
Ethyl carbamate		4.3e-04
Ethyl ether	1.7e-02	2.9e-03
Ethylbenzene	1.0e+00	7.4e-02
Ethylene oxide		6.3e-04
Ethylenedibromide		3.3e-03
Ethyleneimine		1.7e-04
Ethylenethiourea		1.7e-04
Ethylphenol, p-	3.5e-02	1.4e-02
Fluoranthene		3.6e-01
Formaldehyde		2.2e-03
Glycerol	1.4e-04	2.9e-05
Heptachlor		1.1e-02
Heptanol	3.8e-02	1.9e-02
Hexachlorobenzene		2.1e-01
Hexachlorobutadiene		1.2e-01
Hexachloroethane		4.2e-02
Hexamethylphosphoramide		1.6e-04
Hexanol	3.0e-02	1.3e-02
Hydrazine/Hydrazine sulfate		4.1e-05
Indeno(1,2,3-CD)pyrene		1.9e+00
Isophorone		4.2e-03
Lindane		1.4e-02
Mechloroethamine		1.2e-03
Methanol	1.6e-03	3.5e-04
Methoxyethanol, 2-		1.9e-04

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Methoxypropan-2-ol, 1-		4.0e-04
Methyl ethyl ketone	5.0e-03	1.1e-03
Methyl Hydroxybenzoate	9.1e-03	5.2e-03
Methyl iodide		3.1e-03
Methylaziridine, 2-		3.2e-04
Methylene bis(2-chloroanilane), 4,4-		2.8e-02
Methylene bis(N,N'dimethyl)aniline, 4,4-		1.3e-01
Methylene chloride		4.5e-03
Methylenedianiline, 4,4'		1.6e-03
Michler's ketone		3.4e-02
Mustard Gas		5.6e-03
Naphthalene		6.9e-02
Naphthol, b-	2.8e-02	2.6e-02
Naphthylamine, 1-		1.0e-02
Naphthylamine, 2-		1.1e-02
Nitrilotriacetic acid		9.7e-05
Nitro-o-anisidine, 5-		2.5e-03
Nitrobiphenyl, 4-		5.5e-02
Nitrofen		3.0e-01
Nitrophenol, 2-	1.0e-01	5.0e-03
Nitrophenol, 2-amino-4-	7.0e-04	2.0e-03
Nitrophenol, 3-	5.6e-03	7.1e-03
Nitrophenol, 4-	5.6e-03	6.1e-03
Nitrophenol, 4-amino-2-	3.0e-03	1.1e-03
Nitropropane, 2-		1.0e-03
Nitroso-di-n-butylamine, n-		4.8e-03

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Nitroso-N-ethylurea, n-		5.4e-04
Nitroso-N-methylurea, n-		4.3e-04
Nitrosodiethanolamine, n-	5.0e-06	2.2e-05
Nitrosodiethylamine, n-		1.2e-03
Nitrosodiphenylamine, p-		3.6e-02
Nitrosomethylvinylamine, n-		5.7e-04
Nitrosomorpholine, n-		1.8e-04
Nitrosonornicotine, n-		1.7e-04
Nitrosopiperidine, n-		2.5e-05
Nonanol	6.0e-02	7.3e-02
Octanol	6.1e-02	3.9e-02
Parathion		1.7e-02
PCB-chlorobiphenyl, 4-		1.3e+00
PCB-hexachlorobiphenyl		7.1e-01
Pentachloronitrobenzene		5.9e-02
Pentachlorophenol		6.5e-01
Pentanol	6.0e-03	7.1e-03
Pentanone, 4-methyl, 2-		3.3e-03
Phenanthrene		2.3e-01
Phenol	8.2e-03	5.5e-03
Phenol, 4,6-dinitro-2-,methyl-		3.8e-03
Propanol	1.7e-03	1.3e-03
Propiolactone, beta-		3.3e-04
Propylene oxide		8.9e-04
Resorcinol	2.4e-04	1.5e-03
Safrole		1.5e-02

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
Styrene	6.7e-01	5.5e-02
Styrene oxide		4.9e-03
TCDD		1.4e+00
Tetrachlorethylene	3.7e-01	4.8e-02
Tetrachloroethane, 1,1,2,2-		9.0e-03
Thioacetamide		2.1e-03
Thiodianiline, 4,4-		2.5e-03
Thiourea	9.6e-05	1.4e-04
Thymol	5.3e-02	5.1e-02
Toluene	1.0e+00	4.5e-02
Toluidine hydrochloride, o-		2.1e-03
Toluidine, o-		3.7e-03
Toxaphene		1.5e-02
Trichlorobenzene, 1,2,4-		1.0e-01
Trichloroethane, 1,1,1-		1.7e-02
Trichloroethane, 1,1,2-		8.4e-03
Trichloroethylene	2.3e-01	1.6e-02
Trichlorofluoromethane		1.7e-02
Trichlorophenol, 2,4,6-	5.9e-02	5.0e-02
Tris(2,3-dibromopropyl)phosphate		3.6e-04
Tris(aziridinyl)-para-benzoquinone		8.3e-06
Urea	1.2e-04	2.6e-05
Vinyl bromide		5.5e-03
Vinyl chloride		7.3e-03
Water	1.5e-03	1.6e-04
Xylene, m-		8.0e-02

TABLE B-10

**Experimentally Measured and Estimated  
Permeability Coefficient Values (Kp) for  
Chemicals in Aqueous Media**

<b>Chemical</b>	<b>Measured Kp (cm/hr)</b>	<b>Estimated Kp (cm/hr)</b>
<b><u>Inorganics:</u></b>		
Cadmium chloride	1e-03	
Sodium chromate	2e-03	
Sodium dichromate	1e-03	
Chromium chloride	1e-03	
Cobalt chloride	4e-04	
Lead acetate	4e-06	
Mercuric chloride	1e-03	
Methyl mercury-dicyandiamide	1e-03	
Potassium mercuric-chloride	3e-03	
Nickel chloride	1e-04	
Nickel sulfate	9e-06	
Silver nitrate	6e-04	
Zinc chloride	6e-04	

## K. Absorption Efficiency

As discussed in Section 7.2.3, the Relative Absorption Factor (RAF) is used to adjust the calculated exposure to a given chemical so that it is comparable to the toxicity information for that chemical. A unique RAF should be estimated for a chemical for each combination of toxicity value and route of exposure. To estimate an RAF, two factors must be identified:

- (1) the absorption efficiency for the chemical via the route and medium of exposure being evaluated for the disposal site; and
- (2) the absorption efficiency for the route and medium of exposure in the experimental study which is the basis of the dose-response value for the chemical in question.

The RAF is calculated as follows:

$$RAF = \frac{AbsorptionEfficiency_{SITEroute/mediumofexposure}}{AbsorptionEfficiency_{STUDYroute/mediumofexposure}}$$

In the absence of readily available site-specific and chemical-specific information, the default absorption efficiencies in Table B-11 can be used to estimate an RAF. However, it must be stressed that the use of generic absorption efficiency data in a risk assessment will increase the uncertainty in the risk assessment results. This is because there is a wide variation in absorption efficiency among chemicals, even between chemical within the same class. Thus, the default values in Table B-11 should only be used as a last resort when, after a thorough literature search, the risk assessor is unable to find absorption efficiency data specific to the site and the chemical of interest.

Table B-11 below provides default absorption efficiencies for four classes of chemicals; volatile organics, semi-volatile organics, pesticides and metals/inorganics. The first part of Table B-11 provides default absorption efficiencies for various *site* routes and media of exposure. The second part of Table B-11 provides default absorption efficiencies for various *study* routes and media of exposure. To estimate an RAF, select the absorption efficiency that corresponds to the class of chemical of concern and the exposure that is being evaluated at the site. Then select the absorption efficiency that corresponds to the way in which the chemical was administered in the study on which the toxicity value for the chemical of interest is based. This information is typically available as part of the documentation of toxicity values published by EPA in IRIS and HEAST. In addition, the *Risk Assessment ShortForm - Residential Scenario* provides this information for a variety of chemicals. The RAF is calculated as the ratio of the two values, as shown in the equation above.

**TABLE B-11. DEFAULT ABSORPTION EFFICIENCIES**

ROUTE/MEDIUM OF EXPOSURE	Volatile Organics	Semi-Volatile Organics	Metals/Inorganics
<b>SITE</b>			
Soil Ingestion	0.99	0.91	0.39
Soil Dermal Contact	0.11	0.17	0.03
Water Ingestion	0.99	0.92	0.4
Produce Ingestion	0.99	0.92	0.39
<b>STUDY</b>			
Gavage: Oil	1	0.91	Not avail.
Drinking Water	1	Not avail.	0.55
Food	Not avail.	0.95	0.21
Injection	1	1	1
Inhalation	0.91	Not avail.	Not avail.
Dermal Contact	0.11	0.14	0.017

## L. Exposure Frequency

### 1. Utility Worker

The default exposure frequency for a utility worker is one day per year. This represents a conservative estimate of the frequency of exposure to contaminated soil or vapors at depth that would be experienced by a utility worker, given the frequency of utility repairs, the time needed for repairs and the rotation of work crews. This default frequency is based on discussions with utility companies.

### 2. Residential Scenario

The default exposure frequency for exposure to contaminated soil at a residential property is 5 days per week during the months of April through October. This default exposure frequency represents an estimate of the frequency of exposure that a receptor is likely to experience to contamination present at his/her residential property given full and unrestricted use of the property.

An exposure frequency of 5 days per week should also be used when evaluating indoor exposures to dust/soil whose source is outdoor soil, during the months when outdoor exposure does not occur.

### 3. Construction Worker

For a construction worker scenario, the default exposure frequency is 5 days per week for 6 months. This represents a conservative estimate of the frequency of exposure to contaminated soil or vapors that would be experienced by a construction worker, given the typical duration of a construction project.

### 4. Other Scenarios

Default exposure frequencies for other scenarios such as Recreational, Trespasser and Swimming are not provided because exposure frequencies for these scenario may vary too greatly depending on site-specific situations. The risk assessor should develop site-specific exposure frequencies for exposures scenarios that are not provided here.

## **APPENDIX C**

### **PROBABILISTIC EXPOSURE**

### **ASSESSMENT**

## APPENDIX C: PROBABILISTIC EXPOSURE ASSESSMENT

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A Draft of this Section is expected to be available in the fall of 1995.

Copies of the Probabilistic Exposure Assessment guidance will be available through the MADEP Bulletin Board System and through the MADEP InfoLine/MCP Hotline.

Please call the MCP Hotline for the latest information on the schedule for this guidance.

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## **APPENDIX D**

### **DISCUSSION OF TECHNICAL ISSUES**

#### **IN**

### **FISH SAMPLING**

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## **APPENDIX D: DISCUSSION OF TECHNICAL ISSUES IN FISH SAMPLING**

### **INTRODUCTION**

The determination of chemical concentrations in the tissues of aquatic biota can be undertaken for many reasons. The topics and issues presented in the following paragraphs are intended to serve as a guide for the design of these types of programs. Detailed protocols for the component parts of the guidance are available in other sources cited in the text. While the majority of aquatic species sampled in contaminant monitoring programs for the state are fish, there are situations when aquatic invertebrates may be the sampling target. The following information is generally applicable to both groups of organisms with exceptions as noted.

### **STEP 1: DEFINITION OF SAMPLING OBJECTIVES**

Contaminant monitoring in biota may be undertaken for a variety of reasons and it is important at the start of the design of any program to clearly define why the sampling is to be performed in order to set the stage for proper design of the study. Possible objectives include: the description of the spatial or temporal variability in specific chemicals for use as sentinels of environmental quality; the ascertainment of contaminant concentrations in organism tissues for estimating human health hazards posed by ingestion of those tissues; and determining the impact of identified sources of disturbance using control sites (if available) and before and or after the impact event samples.

If sampling is being performed for use in health risk assessment, choices to be made in species selection, sample preparation and analysis and power of the sampling design may differ from those made for other types of programs. A survey may have different requirements than a study being undertaken to determine if impacts have occurred as a result of some chemical release.

Once the sampling objectives have been clearly stated, the details of the sampling program such as specification of target species and analytes, statistical design, sampling methods, sample handling and preservation, analytical methods can be completed.

## IDENTIFICATION OF TARGET SPECIES

The choice of species will be determined in part by the objectives of the study. A particular population of fish or invertebrates may be of interest or a community may be of interest. A fishery resource is often the target of interest. In cases where aquatic species are being used as sentinels of environmental quality, one tactic is to choose species which have the greatest likelihood of accumulating and retaining the target chemicals. Older or larger specimens which have had longer periods to accumulate the chemicals are good choices as are organisms with a high fat content or those whose life history and food preferences would predispose them to greater exposures to the chemicals. Many organic compounds are lipophilic and tend to sequester in lipid rich tissues. Therefore species with higher fat contents often have higher organic chemical concentrations than do relatively lean individuals. Organisms who feed on trophic levels where chemicals may be sequestered or cycled through also are good choices for maximizing the chances of detecting chemicals in biota in an aquatic ecosystem. For example, bottom-feeding fish and deposit feeding invertebrates often may have greater exposures to chemicals than those that feed in the water column. Catfish and suckers in freshwaters; cod, flounder, deposit-feeding polychaete worms and bivalve molluscs, and lobsters in marine waters would all fit this criterion. When the chemical of interest is one which is known to biomagnify in a food web, such as mercury, PCBs or DDT, choosing a species further up the food web will enhance the chances for quantifying the chemical in aquatic species. Possible species meeting this specification are pike, chain pickerel and salmon in freshwater systems and striped bass, bluefish, tuna, and other gamefish in the marine environment.

One of the problems which may be encountered with some species, particularly in localized freshwater environments is the availability of sufficient numbers of individuals to meet the requirements of the study.

## SAMPLING METHODS

The capture methods for the target species will vary dependent upon the species and type of environment being sampled. In freshwater systems, a variety of methods often is more productive than reliance on one capture method. Seining may work well for smaller fish in waters with enough shallow habitat to permit seining. In deeper waters for larger fish, box, pound or gill nets may be used. Angling with rod and reel often is effective for smaller numbers of individuals. Electroshocking can be used in more confined locales. In more open, deeper waters with access to larger vessels, trawling with various types of nets can be used. Sessile or infaunal benthic invertebrates can be captured by hand or remotely with grabs and dredges (Holme and McIntyre, 1971).

## SAMPLE HANDLING CONSIDERATIONS

There are three issues to be considered here: pretreatment of individuals; preservation; and dissection. For some species such as biota that feed on media that may be contaminated, it may be advantageous to allow the organisms to depurate their gut contents prior to preservation. The objectives of the sampling program will determine whether this should be done. In practice, bivalves and worms are the taxa where depuration may be most often used. In cases where individual tissues will be excised, there will be no need to depurate. In cases where, the whole organism is to be analyzed, it may be useful to permit the animals to evacuate their guts if total body burdens of chemicals are to be determined. Depuration can usually be accomplished by placing the organisms in clean water with no sediment for 24 hours.

The order of preservation and dissection is usually dependent upon the circumstances under which sampling is carried out. The decision as to whether intact individuals or specific tissues are analyzed depends upon the objectives of the sampling program. Some species may be too small for practical analysis of individual tissues for regulatory purposes. Analysis of intact individuals gives a gross estimate of the amount of a chemical within the organism, but is not sufficient if specific tissues are of concern. Chemicals are usually sequestered in specific organs or tissues. Those tissues having little of the chemical "dilute" the chemical that is concentrated in other tissues when whole samples are homogenized prior to analysis. This situation limits the detection capabilities for the chemicals in the tissues. When specific tissues are analyzed, analytical detection capabilities can be focussed upon those tissues where the chemical is most likely to be found and hence the chances of detecting the chemical will be maximized. Specific tissues may be analytical targets when information on partitioning on the chemicals of interest within the body is sought or when there is interest in specific tissues from an interpretative perspective. For example, in cases where human health risks from ingestion of chemically contaminated fish are the primary concern, it makes most sense to analyze those tissues that the consumer is exposed to, i.e. the muscle in most cases.

If whole organisms are to be analyzed, then they should be sacrificed as appropriate to the species, placed on ice (usually for no more than several hours during transport to a lab) until they can either be analyzed or frozen for storage. If individual tissues are to be analyzed, dissection may take place immediately after sacrifice if suitably clean conditions for the contaminants of interest can be established. Guidelines for quality control during this phase are contained in USEPA 1993. Otherwise, the intact specimens should be placed on ice until either frozen or ready for analysis in the lab. When ready for analysis, frozen specimens can be thawed and tissues dissected. With post-freezing dissection, or freezing of specific tissues, there is the possibility that cell lysis from ice crystals has taken place with concomitant loss of interstitial fluids and any associated chemicals.

## STATISTICAL CONSIDERATIONS

One of the critical choices in the design of aquatic biota sampling programs is the choice of numbers of samples for analysis. This choice should be governed by the objectives of the sampling program, the underlying statistical design and the available financial resources. This presentation of sampling considerations is not inclusive and the reader is therefore cautioned to adhere to the principles of good experimental design when designing their sampling program. The two main choice alternatives for numbers of samples relate to whether to analyze individual samples or to composite individuals and analyze these pooled samples. The considerations associated with both options are presented in Table D-1.

Table D-1  
Considerations Associated with Analysis  
of Individual Samples and Composites

	Individual	Composite
ADVANTAGES	<ul style="list-style-type: none"><li>* provides most complete information</li><li>* allows most powerful design</li></ul>	<ul style="list-style-type: none"><li>* less expensive</li><li>* useful for rough look</li></ul>
DISADVANTAGES	<ul style="list-style-type: none"><li>* more expensive</li><li>* requires larger numbers of individuals</li></ul>	<ul style="list-style-type: none"><li>* no estimate of between individual variance</li><li>* loss of statistical power</li><li>* poorly developed sampling statistics</li></ul>

Analysis of composite samples has gained favor because of the lessened costs associated with the analysis of a few pools, even though the total number of fish included may be the same as would be required for analysis of individuals. When samples are pooled and analyzed, a single concentration is produced and any information on between-individual variance is lost. This lost estimate of between-sample variance precludes testing between-group differences when pools are involved.

For studies where individual samples will be analyzed, methods for the determination of the appropriate numbers of individuals can be found in Green (1979), Cochran (1977), and USEPA 1993. The best sample number is the largest that can be accommodated. Arguments for large sample numbers are that most statistical analyses tend to be robust in the face of violations of assumptions if they are based on a large number of error degrees of freedom. Precision estimates of mean values also will increase with sample numbers, but the magnitude of the reduction is subject to a law of diminishing returns (Green 1979).

The procedure involved is one of first specifying the hypothesis to be tested with a sampling program; such as "the mean values of mercury concentrations in lobster hepatopancreas from Quincy Bay are the same as those from Massachusetts Bay". The statistical test which will be used to test the hypothesis (often the t-test or analysis of variance for differences between groups) is then identified. The magnitude of change or difference between groups one wants to be able to detect and the acceptable risks of making an error must be specified. For instance, in this example with lobsters, the investigator might determine that he wants to be able to detect a difference of 50% in the concentrations between the two areas with a 1-in-20 chance of being wrong in the conclusion that the groups are different (or stated alternatively with a 95 % confidence that they are indeed the same).

A priori estimates of the sample means and standard deviations are required. This information is not often at hand for the particular species or contaminant of interest. Several avenues are available for obtaining these values. Ideally, preliminary sampling should be performed to provide estimates of the mean and standard deviation. Resources and time are seldom available to permit this step, so a second alternative is to use values from the literature or from other similar studies. While sample variances would be expected to differ between species within a phylum or areas, examination of a large enough data set from the literature may help identify some likely values for the variance and place bounds on the range of variances that have been determined. With this information in hand for two sample tests, the traditional formula describing the confidence limits about a mean in terms of the sample mean, standard deviation and number of samples can be used to solve for the number of replicate samples needed to obtain the desired sampling objectives.

Regrettably in freshwater fish sampling, all of these considerations often become academic because of the difficulty of obtaining adequate numbers of fish in small water bodies.

Variance in tissue or whole body concentrations of most anthropogenic chemicals is also determined by the condition of the organism and its age/size. Water and lipid content can change seasonally in some species and there are large differences in lipid contents between species of fish. The age of an organism also may be a determinant of the tissue chemical concentration. Older individuals of a species will tend to have higher concentrations of chemicals which bioaccumulate than younger ones. These sources of variance can be addressed in two ways when executing a sampling program.

The variation due to seasonally changing water and lipid contents can be addressed first by taking samples for comparison during the same season. Times when gametogenesis and physiological processes associated with spawning are taking place should be avoided.

Differing degrees of tissue hydration introduce variation into the data when concentrations of chemicals in tissues are expressed on a mass per unit wet weight basis. This method of expressing data is common in the literature related to seafood quality and health risk

assessment issues. The preferred method of data treatment in aquatic research is to express these concentrations on a tissue dry weight basis so that this source of variance can be eliminated. This technique can be applied directly to samples destined for analysis of inorganic compounds. However, for organic compounds which might volatilize during drying, samples can be split and one dried to constant weight to determine the percentage of water and the other sample containing water of hydration analyzed. The mass of chemical value per unit wet weight can then be adjusted for the percentage of tissue hydration determined from the split.

Variation due to varying lipid contents can also be normalized by determining the total lipid content of splits of samples and then normalizing chemical concentrations to lipid contents of the tissues, i.e., expressing values as mass of chemical/mg lipid. This standardization method is not very common in applied monitoring programs and data expressed in this manner may not be directly applicable to data generated in other programs.

Variance due to age/size differences can be addressed in two manners. If sampling from large populations where a wide range of sizes of individuals are present, a spectrum of different sized (aged) in the sampling group can be included so that resultant sampling statistics will represent variance across the population. There may be cases when it is known or suspected a priori that older individuals will likely have the highest concentrations of the chemicals of interest, and sampling effort can therefore be focussed upon that group. An alternative method to account for this source of variance is to use the data generated for the spectrum of ages to determine the mathematical relationship between contaminant concentration and age or body size (length or weight) across the samples and then determine predicted concentrations for a chosen standard sized organism, e.g. a 1 kg fish. All subsequent comparisons for between-group differences are then made on the basis of the common sized organism. A less costly alternative, but one which may miss age/size related differences in tissue concentrations of the chemicals of interest is to only analyze fish of similar sizes.

## ANALYTICAL CONSIDERATIONS

Standardized methods for the analysis of inorganic and organic chemicals in biological tissues are available (EPA 1993). More than one method is available for the analysis of inorganics in tissues. The choice should be made based upon the desired level of detection and the budget available for analysis. A commonly used technique for all metals except mercury is inductively coupled plasma emission spectroscopy (ICP) detection of metals in a digest of the sample. This method requires one digestion and yields data on many analytes with one pass through the instrument detector. This information is usually provided at a flat price for most any of the metals in which one might be interested. The drawback of this method is that it is less sensitive than other alternatives. Mercury is analyzed from digests of samples

by anhydride generation of cold mercury and analysis by atomic absorption spectrophotometry. When lower detection limits are desired for some metals or there are only a few target analytes, flame or graphite furnace atomic absorption spectrophotometry (AA) may be used on the sample digest. This method requires additional instrument setup for each analyte and hence analysis is usually priced by the metal.

If lower detection limits are desired with either method, the analytes may be preconcentrated before analysis with the use of an organic chelator. This additional preparation step adds to the cost of the analysis and is not routinely performed as part of most survey programs. It requires additional and more sophisticated laboratory facilities, including clean rooms or work spaces, which are not found in many routine service laboratories.

## **REFERENCES FOR APPENDIX D**

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Cochran, W.G. 1977. Sampling Techniques. 3<sup>rd</sup> Edition. Wiley, N.Y. 428 pp.

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Holme, N.A. and McIntyre, A.D. 1971. Methods for the Study of Marine Benthos. IBP Handbook No. 16. Blackwell Scientific Publications, Oxford. 334p.

United States Environmental Protection Agency (USEPA). 1993. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Fish Sampling and Analysis, Volume 1. Office of Water. EPA 823-R-93-002.

## **APPENDIX E**

### **REFERENCES FOR POTENTIALLY APPLICABLE OR SUITABLY ANALOGOUS STANDARDS**



## **APPENDIX E: REFERENCES FOR POTENTIALLY APPLICABLE OR SUITABLY ANALOGOUS STANDARDS**

The MCP requires a comparison of site concentrations to Applicable or Suitably Analogous Standards as a component of Method 3 Risk Characterizations. To achieve a condition of No Significant Risk of Harm to human health, two tests must be met. First, the quantitative estimates of risk resulting from the site specific risk assessment cannot exceed MCP risk management criterion. Second, no exposure point concentration may exceed an applicable or suitably analogous human health standard (310 CMR 40.0993(7). Similarly, a Method 3 Environmental Risk Characterization must include comparison of environmental concentrations to any applicable or suitably analogous standards as well as a site specific evaluation of risk. A description of potentially Applicable or Suitably Analogous Standards for human health and environmental risk characterization follows.

### **Massachusetts Maximum Contaminant Levels**

The Massachusetts Maximum Contaminant Levels (MMCLs) are the Massachusetts Drinking Water Standards. The MMCLs comprise the Massachusetts MCLs listed in 310 CMR 22.00 and the MCLs set by EPA. DEP/Office of Research and Standards updates the MMCLs semiannually in Drinking Water Standards & Guidelines for Chemicals in Massachusetts Drinking Water. Only the MMCLs are Applicable or Suitably Analogous Standards under the MCP; drinking Water Guidelines are not.

### **National Ambient Air Quality Standards**

EPA has promulgated National Ambient Air Quality Standards (NAAQS) for six pollutants: sulfur oxides, particulate matter, carbon monoxide, ozone, nitrogen dioxide and lead. The primary and secondary standards are listed at 40 CFR 50.00. National Primary Ambient Air Quality Standards are Applicable or Suitably Analogous Standards for public health under the MCP, while the National Secondary Ambient Air Quality Standards are Applicable or Suitably Analogous Standards for public welfare. Only a primary standard has been published for carbon monoxide. Both primary and secondary standards have been promulgated for the remaining five pollutants.

## Massachusetts Surface Water Quality Standards

Massachusetts Surface Water Quality Standards are applicable to concentrations of oil and/or hazardous material in surface water. These standards are promulgated at 314 CMR 4.00. Massachusetts Surface Water Quality Standards consist of numerical values for dissolved oxygen, temperature, pH, fecal coliform, solids, color and turbidity, oil and grease, and taste and odor. Narrative standards are set for aesthetics, bottom pollutants or alterations, nutrients, radioactivity and toxic pollutants.

Of the narrative standards, the one for toxic pollutants is most relevant for oil and hazardous material releases from 21E sites. The text (314 CMR 4.05(5)(e)) is as follows:

*(e) Toxic Pollutants - All surface waters shall be free from pollutants in concentrations or combinations that are toxic to humans, aquatic life or wildlife. Where the Division determines that a specific pollutant not otherwise listed in these regulations could reasonably be expected to adversely effect existing or designated uses, the Division shall use the recommended limit published by EPA pursuant to Section 304 (a) of the Federal Act as the allowable receiving water concentration for the affected waters unless a site specific limit is established. Site-specific limits, human health risk levels and permit limits will be established in accordance with the following:*

1. Site-specific limits: *Where recommended limits for a specific pollutant are not available or where they are invalid due to site-specific physical, chemical or biological considerations, the Division shall use a site-specific limit as the allowable receiving water concentration of the affected waters. In all cases, at a minimum, site-specific limits shall not exceed safe exposure levels determined by toxicity testing using methods approved by the Director.*

**PROGRAM/POLICY NOTE:** This provision for applying site-specific limits in lieu of designated surface water standards may not apply to MCP sites, since the standards are applied as part of a site-specific risk assessment, and since the Director/Division of Water Pollution Control will not be involved in the review of individual MCP risk assessments.

2. Human Health Risk Levels: *The human health-based regulation of toxic pollutants shall be in accordance with guidance issued by the Department of Environmental Protection's Office of Research and Standards. The Division's goal shall be to prevent all adverse health effects which may result from the ingestion, inhalation or dermal contact with contaminated waters during their reasonable use as designated in these regulations. When this goal is not attainable, the guidance will specify acceptable excess lifetime cancer risk levels for carcinogens and methodology to be used for their*

*application. The Division may also consider factors of practicability and feasibility when deriving effluent limitations from the human health-based criteria.*

3. *Accumulation of Pollutants:* *Where appropriate the Division shall use an additional margin of safety when establishing water quality based effluent limits to assure that pollutants do not persist in the environment or accumulate in organisms to levels that: (a) are toxic to humans or aquatic life; or (b) result in unacceptable concentrations in edible portions of marketable fish or shellfish or for the recreational use of fish, shellfish, other aquatic life or wildlife for human consumption.*
4. *Public Notice:* *Where recommended limits or site-specific limits are used to establish water quality based effluent limitations they shall be documented and subject to full intergovernmental coordination and public participation as set forth in 314 CMR 2.00 "Permit Procedures".*

In the regulations cited above, the phrase "*the Division shall use the recommended limit published by EPA pursuant to Section 304 (a) of the Federal Act*" means that the EPA Ambient Water Quality Criteria (AWQC) are adopted as Massachusetts Surface Water Quality Standards. The derivation of the AWQCs is documented in Quality Criteria for Water (EPA 1986, with updates). Note that only actual criteria are considered applicable standards. Quality Criteria for Water (EPA 1986) presents LOAELs for toxics for some substances for which criteria could not be developed due to insufficient data. However, those LOAELs are not considered applicable standards.

EPA has published criteria for both the protection of aquatic life and for the protection of human health. Only the criteria for the protection of aquatic organisms are applicable standards for environmental risk characterization. The criteria that are based on drinking water and fish consumption are applicable standards for a human health risk characterization.

There are currently no limitations on the applicability of surface water standards established for the protection of aquatic life. Surface Water Standards apply to all surface water in the state. All surface water in Massachusetts is currently classified as:

- A - public water supply
- B - fishable/swimmable
- SA - saltwater open shellfishing
- SB - salt water restricted shellfishing

There is no surface water in the state in which aquatic life is explicitly not protected. Thus, surface water standards that protect aquatic life (marine and freshwater Ambient Water Quality Criteria) apply to all surface water bodies in Massachusetts.

Application of the Ambient Water Quality Criteria for protection of aquatic life requires consideration of two site-specific factors: hardness and dissolved metals. For the purpose of identifying a site-specific Surface Water Quality Standard, the listed Ambient Water Quality Criterion for a metal may be adjusted in two ways. The first is that the hardness-dependent criteria for metals should be adjusted for the hardness of the surface water at the site. The second is that dissolved metals may be evaluated by adjusting the criteria for that purpose.

#### Hardness:

The EPA Ambient Water Quality Criteria for cadmium, chromium III, copper, lead, mercury, nickel, silver, and zinc are all hardness-dependent. For a given aqueous concentration, toxicity increases as hardness decreases. In general the listed values are based on an assumed hardness of 100 mg/L, but hardness in Massachusetts water bodies is typically about 25 mg/L. For a standard to be protective at a specific site where hardness is lower than 100 mg/L, the listed values should be adjusted.

#### Dissolved Metals:

The EPA will promulgate new regulations for applying Ambient Water Quality Criteria to dissolved metals in the summer of 1995.

## **APPENDIX F**

### **FRAMEWORK FOR**

### **METHOD 1**



## APPENDIX F: FRAMEWORK FOR METHOD 1

The following topics have been identified for assessing the completeness of Method 1 Risk Characterization Reports. Ten main subject areas have been delineated. Each of these topics should be addressed in the risk characterization. Depending upon site specific considerations, some areas may require a more detailed discussion than others. This outline has been prepared as a simple guide to determine whether a report has addressed the major points of a Method 1 risk characterization. It does not substitute for a thorough knowledge of the MCP requirements or current risk assessment methodologies. Specific references to the *Massachusetts Contingency Plan (MCP) 310 CMR 40.0000* and this *Guidance for Disposal Site Risk Characterization - In Support of the Massachusetts Contingency Plan (Risk Assessment Guidance/RAG)* have been provided. These references provide a more detailed discussion of the particular subject area under consideration.

**NOTE:** *This guidance is applicable to reports conducted in accordance with the 1993 MCP and the 1995 amendments.*

### 1. Adequate Site Characterization

- \* Have all the impacted media been assessed?
- \* Have all the sources of contamination been identified?
- \* Has the extent of the release, in each impacted media, been defined?
- \* Are the data representative of site contaminant conditions?
- \* Has a list of contaminants been identified for the site? Are all the chemicals on that list considered to be Contaminants of Concern to be carried through the risk assessment process? If some chemicals have been eliminated, what was the basis for their elimination and was it proper?

For additional discussion please see:

*The Massachusetts Contingency Plan (MCP) 310 CMR 40.0904 Site Information required for Risk Characterization; and the Guidance for Disposal Site Risk Characterization - In Support of the Massachusetts Contingency Plan, Section 1.3 Level of Effort Appropriate to Action Taken, Section 2.2 Determining the Nature and Extent of Contamination and Section 2.4 Contaminants of Concern.*

## **2. Site Activities & Uses**

- \* Have all current uses been considered and evaluated at the site?
- \* Have the foreseeable uses been identified and evaluated for the site?
- \* Has the use of Activity and Use Limitations been proposed to eliminate any exposure pathways?

For additional information please see:

*MCP 310 CMR 40.0923 Identification of Site Activities and Uses; and  
RAG Section 2.1. Current and Foreseeable Use.*

## **3. Imminent Hazard Evaluation**

- \* Are there conditions at the site which may pose an Imminent Hazard?
- \* Has the Imminent Hazard risk characterization been properly conducted?
- \* Is the outcome of the Imminent Hazard risk characterization clearly stated?

For additional information please see:

*MCP 310 CMR 40.0950 Imminent Hazard Evaluations; and  
RAG Section 10.0 Imminent Hazard Evaluations.*

## **4. Appropriateness of the Use of Method 1**

- \* Are media other than soil and groundwater contaminated at the site?
- \* Does exposure to human receptors occur predominantly through contact with soil and groundwater?
- \* Are hazardous materials which are known to bio-accumulate present in the top two feet of soil?
- \* Do Method 1 standards exist for all contaminants of concern?

For additional information please see:

*MCP 310 CMR 40.0942 Selection of Method to Characterize the Risk of Harm to Health, Public Welfare and the Environment; and 40.0971 Applicability of Method 1; and RAG Section 3.1 Restrictions on the Use of Method 1 and Section 5.0 Method 1 with particular emphasis on section 5.1 Introduction, Section 5.2 Applicability, and Section 5.3 General Approach.*

## 5. Groundwater & Soil Categorization

- \* Has the groundwater at the site been properly categorized?  
Does more than one category apply to the site?

NOTE: GW-3 applies everywhere in the Commonwealth based upon discharge of groundwater to surface water. GW-2 applies when the average annual depth to groundwater is <15 feet, and there is an occupied structure within 30 feet of the contaminated groundwater. GW-1 applies in areas designated to be protected as drinking water resources. The specific criteria determining a GW-1 area include: Zone II areas, Interim Wellhead Protection Areas, Potentially Productive Aquifers, Zone A of a Class A Surface Water, within 500 feet of a private well or 500 feet from a public supply system.

- \* Has the soil at the site been properly categorized?  
Is more than one soil category applicable at the site?

NOTE: The categorization of soil is based upon the site use and activities. In determining the appropriate soil category you must consider: the type of receptor present (children v. adults only), the frequency of use of the site, the intensity of the activities occurring at the site and the accessibility of the soil.

For additional information please see:

*MCP 310 CMR 40.0932 Identification of Applicable Groundwater Categories and 40.0933 Identification of Applicable Soil Categories and Table 40.0933(9) Soil Category Selection Matrix - Human Exposure Potential; and RAG Section 5.7 Soil and Groundwater Categorization.*

## 6. Exposure Point Concentrations

- \* Is it clear how the soil exposure point concentrations were determined?

NOTE: The soil exposure point concentrations should only include areas which are contaminated. Hot spot areas should be addressed as separate exposure point concentrations.

- \* Is it clear how the groundwater exposure point concentrations were determined?

NOTE: Each monitoring well should be considered a separate exposure point. Data for each individual well may be averaged over reasonable time periods.

- \* Have Hot Spots been identified? Is the report clear on how the Hot Spots were identified and delineated?

For additional information please see:

*MCP 310 CMR 40.0926 Identification of Exposure Point Concentrations and 40.0973(3) Method 1 Risk Characterization; and RAG Section 5.9 Identification of Exposure Points.*

## **7. Background Concentrations**

- \* Has the Risk Assessment identified "background levels" of oil or hazardous materials at this location?
- \* Have the levels been accurately established and documented in the report?
- \* Were background samples collected in area separate from this release or any other release?
- \* If literature values were cited, were adequate references provided for the background data?
- \* Was the comparison between site data and background concentrations conducted appropriately?

For additional information please see:

*MCP 310 CMR 40.0006 Terminology, Definitions and Acronyms, 40.0904(2)(b) Extent of Release; and RAG Section 2.3 Background, 2.4.4 Contaminants of Concern - Background.*

## **8. Identification of Method 1 Standards**

- \* Does the report identify the correct Method 1 Standards?

For additional information please see:

*MCP 310 CMR 40.0974 Identification of Applicable Groundwater Standards in Method 1 and 40.0975 Identification of Applicable Soil Standards in Method 1; and RAG Section 5.8 Identification of Applicable Method 1 Soil and Groundwater Standards.*

## 9. Evaluation of Risk of Harm to Safety & the Environment

- \* Are there conditions at the site which might pose a risk to safety?
- \* Do conditions at the site warrant a separate Method 3 Ecological Risk Evaluation?

For additional information please see:

*MCP 310 CMR 40.0960 Characterization of Risk to Safety, 40.0942(1) Selection of Method to Characterize the Risk of Harm to Health, Public Welfare and the Environment and 40.0995 Method 3 Environmental Risk Characterization; and RAG Section 5.11 Characterizing Safety Risks, Section 4.0 Characterization of Risk of Harm to Safety, Section 9.0 Environmental Risk Characterization.*

## 10. Conclusions

- \* Does the report state whether a condition of no significant risk of harm to health, safety, public welfare and the environment exists?
- \* Does the report state whether there is a need for the use of Activity and Use Limitations to maintain a condition of no significant risk?

For additional information please see:

*MCP 310 CMR 40.0973(8) Method 1 Risk Characterization and 40.0923(4) and (5) Identification of Site Activities and Uses; and RAG Section 5.12 Drawing Conclusions from a Method 1 Risk Characterization and Section 5.13 Activity and Use Limitations.*

I have the honor to acknowledge the receipt of your letter of the 10th inst. in relation to the matter of the 1st inst. and in reply to inform you that the same has been forwarded to the proper authorities for their consideration.

I am, Sir, very respectfully,  
Your obedient servant,  
J. H. [Name]

I have the honor to acknowledge the receipt of your letter of the 10th inst. in relation to the matter of the 1st inst. and in reply to inform you that the same has been forwarded to the proper authorities for their consideration.

I am, Sir, very respectfully,  
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Your obedient servant,  
J. H. [Name]

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## **APPENDIX G**

### **FRAMEWORK FOR**

### **METHOD 2**



## APPENDIX G: FRAMEWORK FOR METHOD 2

The following framework is presented to assist the risk assessor in determining whether the Method 2 Risk Characterization report being submitted adequately addresses the fundamental points of this approach. The Framework of Method 1 (Appendix E) identifies ten subject areas that should be addressed in a Method 1 Risk Characterization for completeness. These topics are equally applicable to a Method 2 Risk Characterization. When checking a Method 2 Risk Characterization for completeness the first step should be to apply the criteria set forth in the Method 1 Framework. The Method 1 Framework criteria include:

1. Adequate Site Characterization
2. Site Activities & Uses
3. Imminent Hazard Evaluation
4. Appropriateness of the Use of Method 1
5. Groundwater & Soil Categorization
6. Exposure Point Concentrations
7. Background Concentrations
8. Identification of Method 1 Standards
9. Evaluation of Risk of Harm to Safety & the Environment
10. Conclusions

These criteria are identified and discussed in the Framework for Method 1 and thus are only summarized here. In addition to the Method 1 Framework there are particular criteria which must be addressed when Method 2 is used. These topics are identified and discussed briefly below. It is important to remember that this outline has been prepared as a simple guide to determine whether a report has addressed the major points of a Method 2 Risk Characterization. It does not substitute for a thorough knowledge of the MCP requirements or current risk assessment methodologies. Specific References to the *Massachusetts Contingency Plan (MCP) 310 CMR 40.0000* and *this Guidance for Disposal Site Risk Characterization - In Support of the Massachusetts Contingency Plan (Risk Assessment Guidance/ RAG)*.

## 1. Derivation of Additional Standards

- \* Is there a Method 1 Standard available for the selected contaminant of concern?
- \* Have the equations and exposure assumptions promulgated in the MCP been utilized to develop additional standards?
- \* Have all supporting references and outside sources clearly provided?

For additional discussion please see:

*The Massachusetts Contingency Plan (MCP) 310 CMR 40.0983 Derivation of Additional Method 1 groundwater Standards for Use in Method 2 and 40.0984 Derivation of Additional Method 1 Soil Standards for Use in Method 2, and the RAG Section 6.3 Derivation of Additional Method 1 Standards.*

## 2. Modification of Existing Method 1 Soil Standards

- \* Have the Method 1 Soil Standards which were modified been based upon the leaching component, and not upon direct contact? Are the resulting standards no greater than the direct contact standards listed in Table 5 of the MCP 310 CMR 40.0985(6)?
- \* Has a predictive leaching model been used to modify the Method 1 standards?
- \* Has sufficient background information been supplied on the model?
- \* If laboratory tests were utilized to assess fate and transport considerations, has sufficient documentation provided?

For additional discussion please see:

*MCP 310 CMR 40.0985 Determination of Method 2 Soil Standards Considering Leaching Potential; and RAG Section 6.4.*

### 3. Modification of Existing Method 1 GW-2 Standards

- \* Has the existing Method 1 Standard been modified to reflect site specific conditions?
- \* Have the steps taken (including use of predictive models) been identified clearly? Have they been adequately documented?
- \* Has field data been utilized to demonstrate that no exposure is occurring and thus to eliminate the applicability of the Method 1 GW-2 standard?
- \* If field data was utilized, has it been supplied in the report? Has it been adequately documented?

For additional discussion please see:

*MCP 310 CMR 40.0986 Determination of Method 2 GW-2 Standards; and RAG Section 6.4.*

### 4. Modification of Existing Method 1 GW-3 Standards

- \* Has the existing Method 1 Standard been modified to reflect existing site specific conditions?
- \* Have the steps taken to reach that conclusion been clearly identified and documented (including the use of any predictive models)?
- \* Has the existing Method 1 Standard been determined to be inapplicable based upon site specific conditions? If so, has this been adequately documented?
- \* Has the field data or model used to reach this conclusion been identified, documented and discussed?

For additional discussion please see:

*MCP 310 CMR 40.0987 Determination of MCP Method 2 GW-3 Standards; and RAG Section 6.4.*

## 5. Development and Modification of Additional Method 1 Standards

- \* Have additional Method 1 Standards been developed in accordance with the MCP (see above # 1)?
- \* Have the additional Method 1 Standards developed been modified based upon site specific considerations (see above # 2,3 & 4)?

For additional discussion please see:

*MCP 310 CMR 40.0983 through 40.0987; and RAG Section 6.0.*

## 6. Use of Predictive Models

- \* Was a predictive model used to modify or make inapplicable the Method 1 Standards?
- \* Was the type of model employed identified and discussed?
- \* Was sufficient information on the model provided, so that the modifications may be evaluated?

For additional discussion please see:

*MCP 310 CMR 40.0985 through 40.0987; and RAG Section 6.4.1.*

## **APPENDIX H**

### **METHOD 3**

#### **SCOPE OF WORK GUIDANCE**

# THE HISTORY OF THE UNITED STATES

OF THE UNITED STATES OF AMERICA

FROM THE FIRST SETTLEMENTS TO THE PRESENT TIME

BY JAMES M. SMITH

NEW YORK: PUBLISHED BY J. B. LIPPINCOTT & CO.

1850

THE HISTORY OF THE UNITED STATES

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THE HISTORY OF THE UNITED STATES

## APPENDIX H: METHOD 3 SCOPE OF WORK GUIDANCE

### Suggested Outline, Content and Format

This guidance is designed to emphasize the importance of planning when using Method 3 to characterize risk at a disposal site. The Method 3 approach uses site specific information to characterize risk. As a result, each Method 3 risk characterization will be somewhat unique. It is most efficient to discuss the planned approach at the front end of the process prior to actually doing the risk characterization. Placing the emphasis on planning early in the process should aid in providing higher quality risk characterizations and be less costly and more time efficient.

The Scope of Work should seek to provide as much information as possible. The Scope should clearly identify certain activities such as categorizing soil and groundwater and identifying current and reasonably foreseeable use at the disposal site and the surrounding area. Whenever it is possible to provide information up front it should be done. There may be some activities which will only be discussed in the Scope of Work, and not actually performed until the risk assessment itself is done. These proposed activities include such things as providing toxicity profiles or actually conducting the risk characterization. The planned approach for those activities should be clearly described.

This document is designed to be an outline and should be used in conjunction with the *Massachusetts Contingency Plan (MCP) 310 CMR 40.0000, the Guidance for Disposal Site Risk Characterization - In Support of the Massachusetts Contingency Plan*, and current accepted risk assessment practices.

## **I. PRELIMINARY STEPS**

### **A. Identify Current & Reasonably Foreseeable Use of the Site**

The Scope of Work should identify the current and reasonably foreseeable uses of the site and the surrounding area. If the use of an Activity and Use Limitation (AUL) is planned, to lock in a current use this should be discussed. It is important to remember that AULs can not be utilized to limit current exposures, therefore, the Scope should clearly indicate which exposure scenarios reflect current potential exposures, and which represent future conditions.

### **B. Categorize Soil & Groundwater**

The soil and groundwater at the site should be categorized in accordance with 310 CMR 40.0930. This is required for Method 3 Risk Characterizations (310 CMR 40.0993(2)).

### **C. Establish Background**

The Scope of Work should identify how background values will be established for the disposal site. This may include actual environmental data collected in the vicinity or the site, Background values published by DEP, or, as a last resort, background values published in the literature.

## **II. Hazard Identification**

### **A. Identify Contaminants of Concern**

The Scope of Work should contain a list of Contaminants of Concern (COC). The Scope should identify any contaminants at the site which will not be carried through the risk assessment process and include the rationale for eliminating these contaminants. If the final list is not yet available, the Scope should include a tentative list including all the contaminants detected at the site.

### **B. Toxicity Profiles**

A Toxicity Profile describes the potential human health effects posed by the contaminant. Toxicity Profiles should be prepared for each COC identified at the site. In the case where a Method 1 Standard exists for the contaminant, it is not necessary

to prepare a full Toxicity Profile, a Descriptive Summary of the health effects is sufficient. The Scope of Work should identify which contaminants will require toxicity profiles and which will be discussed through the use of Descriptive Summaries.

#### C. Identify Applicable or Suitably Analogous Standards

The Scope of Work should identify what standards will be considered applicable or suitably analogous. Each individual standard need not be listed, but the category should be clearly identified. For example, the Massachusetts Drinking Water Quality Standards promulgated in 310 CMR 22.00 would be considered applicable to all category GW-1 areas. ( Remember, the Method 1 Standards are not considered Applicable or Suitably Analogous Public Health Standards.)

### III. Dose-Response Assessment

The Dose-Response Assessment is the portion of the report which discusses the observed effects in humans and animals associated with exposures to the COC. The dose-response section of the Scope should discuss both threshold (non-cancer) and non-threshold (cancer) effects. The Scope should clearly state what sources will be used to identify dose-response information. The primary sources for this information are the Integrated Risk Information System (IRIS) and the Health Effects Assessment Summary Tables (HEAST). These sources should be utilized when the information needed is available there, otherwise the Scope should identify all sources which will be accessed.

### IV. Exposure Assessment

#### A. Exposure Profiles

An exposure profile identifies how exposures may occur at a disposal site. The Scope of Work should contain a narrative description of each exposure profile for the disposal site. In addition, the information in the narrative should be summarized in tables for easy reference. The exposure profiles should clearly identify all potential:

1. human receptors;
2. exposure points for each receptor
3. exposure routes
4. exposure pathways

An narrative example of an exposure profile is described in Table H-1.

**TABLE H-1**

A disposal site has been adequately characterized and found to have surficial soil contamination with lead and polycyclic aromatic hydrocarbons (PAHs). The site is a residential area. The potential receptors at the site are children and adults living at the site. The exposure points are the yards of the property. The exposure routes include: direct contact with contaminated soil, ingestion of soil and inhalation of fugitive dust.

A summary of the same exposure profile information in tabular form is presented in Table H-2.

**TABLE H-2**  
**Exposure Profile Summary Table**

RECEPTOR	EXPOSURE POINT	EXPOSURE ROUTE
Child (age 1-6)	Residential Yard	Soil Dermal Contact Soil Ingestion Inhalation of Fugitive Dust
Adult	Residential Yard	Soil Dermal Contact Soil Ingestion Inhalation of Fugitive Dust

#### B. Exposure Assumptions

The Scope of Work should identify the exposure assumptions which will be made in the risk assessment. The exposure assumptions made should be realistic and health protective, based upon current and reasonably foreseeable conditions. In some cases the risk assessor may want to evaluate a worst case exposure scenario, as a screening process. For example, assume that the industrial property was a residential property, if the risk assessment demonstrates a level of no significant risk, even if the property was later developed as residential, the risk assessment would be applicable. If this

worst case screening approach is being conducted, the Scope of Work should clearly state that and provide the rationale.

### C. Quantitative Estimates of Exposure

After the Scope of Work has described the exposure profiles for the disposal site, the potential exposures to the receptors must be quantified. The Scope should identify the exposure factors which will be used to estimate the dose of oil or hazardous material experienced by a potential receptor. These factors include:

- \* Concentration of oil or hazardous material
- \* Body Weight
- \* Frequency of Exposure
- \* Duration of the Exposure Event
- \* Duration of the Exposure Period
- \* Relative Absorption Factor
- \* Averaging Period
- \* Units Conversion Factors

The equations to be used to calculate average daily exposures from contamination in air and average daily doses from contamination in all other media should be provided in the Scope.

### D. Exposure Point Concentrations

The Scope of Work should identify how exposure point concentrations (EPCs) will be calculated. If the actual EPCs are listed in the Scope, sufficient detail should be provided so that it is clear as to how the EPCs were calculated.

## V. Risk Characterization

### A. Non-Cancer Risk

The Scope of Work should state that for each human receptor identified cumulative non-cancer risks shall be calculated and compared to a cumulative non-cancer risk limit, which is a Hazard Index equal to one. The Scope of Work should state whether Hazard Indices will be calculated based upon a particular chemicals' mechanism of action and/or target organ(s).

## **B. Cancer Risk**

The Scope of Work should state that for each human receptor identified cumulative cancer risks shall be calculated and compared to a cumulative cancer risk limit of one-in-one hundred thousand.

## **C. Applicable or Suitably Analogous Standards**

The Scope should identify any applicable or suitably analogous standards which exposure point concentrations will be compared to.

## **D. Summary Tables**

The Scope must should state that a clear summary of all Hazard Indices and Cumulative Cancer Risks for each receptor group for both current and reasonably foreseeable uses will be presented in the Risk Assessment Report.

# **VI. Uncertainty Analysis**

The Scope of Work should identify the uncertainties in the risk assessment which will be discussed. The types of uncertainties to be discussed should be identified. Some typical areas of uncertainty encountered in the risk assessment process include:

- \* adequacy of the site characterization
- \* adequacy of the sampling plan
- \* quality of the analytical data
- \* accuracy of any modeling
- \* accuracy of the assumptions concerning frequency, duration and magnitude of exposures
- \* availability and accuracy of the toxicity data
- \* treatment of available analytical data
- \* accuracy of any probabilistic analysis used

## **VII. Shortcuts**

The Scope of Work should clearly state when any streamline approaches are being taken. When for example, a worst case scenario is used to screen out any potential exposures this should be identified. Another commonly used shortcut is the use of the *Risk Assessment Shortform - Residential Scenario*. The Shortform allows the risk assessor to conduct a Method 3 Risk Assessment, without preparing all the site specific exposure information. The default assumptions for a typical residential site are provided in the Shortform.

## **VIII. Public Welfare Risk Characterization**

The scope of Work should state that the risk of harm to public welfare posed by the disposal site will be evaluated. The Scope may contain such factors as deemed appropriate to evaluate this potential harm, such as the presence of nuisance conditions.

## **IX. Characterization of Risk to Safety**

The Scope of Work should state that the risk of harm to safety will be characterized. The Scope should identify any applicable or suitably analogous safety standards.

## **X. Environmental Risk Characterization**

The Scope of Work should state that an Environmental Risk Characterization will be conducted. The extent of information provided in the Scope will depend upon the site specific conditions. The reader is referred to the Method 3 Environmental Risk Characterization Guidance found in Section 9.0 for additional guidance on the initial scoping of an environmental risk characterization.

## **XI. Conclusions**

The Scope of Work should state that the risk assessment report will contain a section concluding whether or not a condition of no significant risk of harm to human health, safety, public welfare or the environment exists.



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## INDEX

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**Commonwealth of Massachusetts  
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